

Kidswell Bio (TYO:4584)

The biosimilar business recorded a profit. A contract with a partner company for the development of SHED is awaited.

◆ 1Q of FY2025/3 Financial Highlights: Consolidated financial results announced

Effective the beginning of the current fiscal year, Kidswell Bio spun off its cell therapy business into a wholly-owned subsidiary, S-Quatre Corporation, and the company (Kidswell Bio on a non-consolidated basis) transitioned to a structure that focuses mainly on the biosimilar business.

The company announced its first quarter results for FY2025/3 on August 14, 2024, with sales of 480 million yen, operating loss of 150 million yen, ordinary loss of 170 million yen, and quarterly net loss attributable to owners of the parent of 170 million yen. As the company has just started consolidating its accounts, year-on-year comparisons are not shown in the earnings report. However, the company commented that the results were in line with its expectations.

The balance sheet shows that the company requires increased working capital in line with the growth of its biosimilar business. In response, the company is in discussions with partner development companies and is implementing measures to improve cash flow and profitability. The company manages working capital flexibly and appropriately in response to increasing demand.

◆ Topics: Turning the biosimilar business profitable, forming a partnership with Chiome Bioscience in the same business, and continuing negotiations with SHED development partner companies

First, the company's biosimilar business recorded a profit, with sales of 480 million yen, gross profit of 220 million yen, operating profit of 30 million yen, ordinary profit of 10 million yen, and quarterly net profit of 10 million yen. According to the company, deliveries of the four biosimilars it supplies have all been on schedule, and demand for GBS-007 and GBS-010, in particular, which have no competing biosimilars, has been extremely strong. The fact that the company has achieved a profit in the face of continued cost pressures due to rising manufacturing costs in overseas markets and the depreciation of the yen is significant. Second, to further expand its biosimilar business, the company has formed a business alliance with Chiome Bioscience, Inc. (hereafter, Chiome). By sharing the human resources and know-how of both companies, which are well versed in biotechnology, it is expected that the efficiency and speed of development of the fifth and subsequent products will be improved. Third, the clinical research on cerebral palsy using autologous SHED, initiated in the previous fiscal year and led by Nagoya University, is progressing smoothly. In addition, preparations for manufacturing the investigational product and consultations with the Pharmaceuticals and Medical Devices Agency are progressing for the clinical trial of allogeneic SHED for cerebral palsy (chronic stage) in Japan, and contract negotiations are progressing with the development partner company that will lead this clinical trial.

◆ Stock Price Trends and Points to Watch in the Future

Since last autumn, the company's share price has generally fluctuated between 120 and 160 yen, with a mid-point of 140 yen. When the stock market fell sharply in early August this year, the company's share price also fell sharply, but it quickly recovered to 130 yen.

This is believed to reflect the company's track record of steadily monetizing the growth opportunities in its biosimilar business, which is less susceptible to economic trends (while also addressing increased working capital and exchange rate fluctuations), and linking this to corporate value, the fact that a path for further earnings and corporate value growth is beginning to emerge, and the expectation that the company's contract with its development partner for SHED in the cell therapy business will be concluded within the fiscal year ending March 2025, as the company has anticipated. As these points progress, the value of each business will become visible, and at the same time, the means of raising funds will become more optimized, and the company will be able to break away from its traditional financial structure, which has seen continuous dilution of the shares. For this reason, the company is attracting much attention in the stock market.

The main points to watch are whether the company will be able to improve the accuracy of its full-year sales guidance of 3.5-4.5 billion yen; whether the company will disclose its profit forecast, which it has not disclosed to date, and whether it will be positive; whether the company will be able to ensure stable supply and profitability of the biosimilars it has already launched, and the optimization of cash flow, the progress of the development of new biosimilars and the results of the collaboration with Chiome Bioscience, and the conclusion of a contract with a development partner in the cell therapy business as mentioned above during the current fiscal year as planned by the company. We should also pay attention to the fact that a weaker yen will lead to cost reductions.

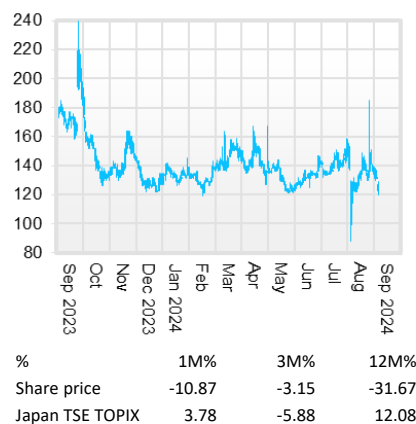
1Q results update

Healthcare

As of September 5, 2024

Share price(9/4)	¥123
52 weeks high/low	¥120/129
Avg Vol (3 month)	626 ^{thou} shrs
Market Cap	¥4.9 bn
Enterprise Value	¥5.6 bn
PER (25/3 CE)	-X
PBR (24/3 act)	8.6 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	39.721 ^{mn} shrs
Listed market	TSE Growth

Share price



Points of interest

Whether or not the accuracy of the guidance of full-year sales of 3.5-4.5 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.

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.

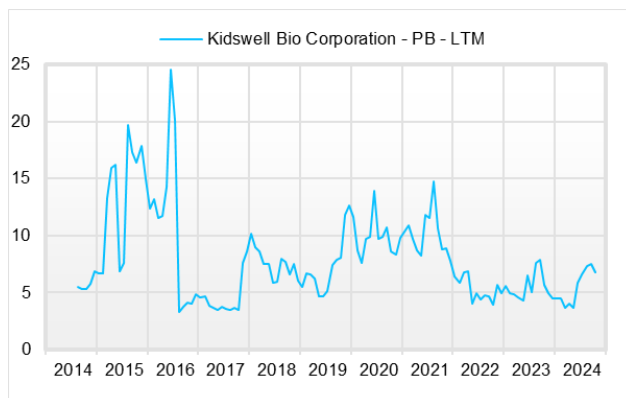
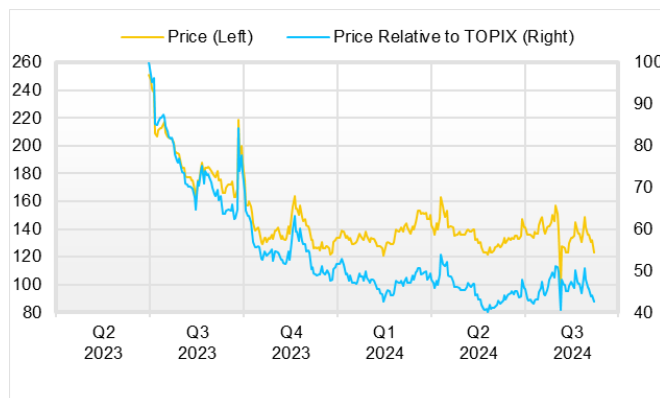
In FY2025/3, SHED development was transferred to the newly established wholly-owned subsidiary S-Quatre Corporation, and the company became a structure that mainly specializes in the biosimilar business. As a result, it became possible to visualize the two businesses' business values and take the most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

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	3,500~4,500
EBIT (Operating Income)	-1,161	-970	-976	-551	-1,336	
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	
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	
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

Outlook for the current fiscal year (ending March 31, 2025) **Kidswell.Bio**

- Due to the difficulty in generating reliable earnings forecast figures for the current fiscal year (ending March 31, 2025) at this time, only sales forecast is provided as a range.
- The forecast of operating income, ordinary income and net income will be provided as soon as the discussions and coordination with partner pharmaceutical companies and CDMO's are completed.

(Unit: thousand yen)

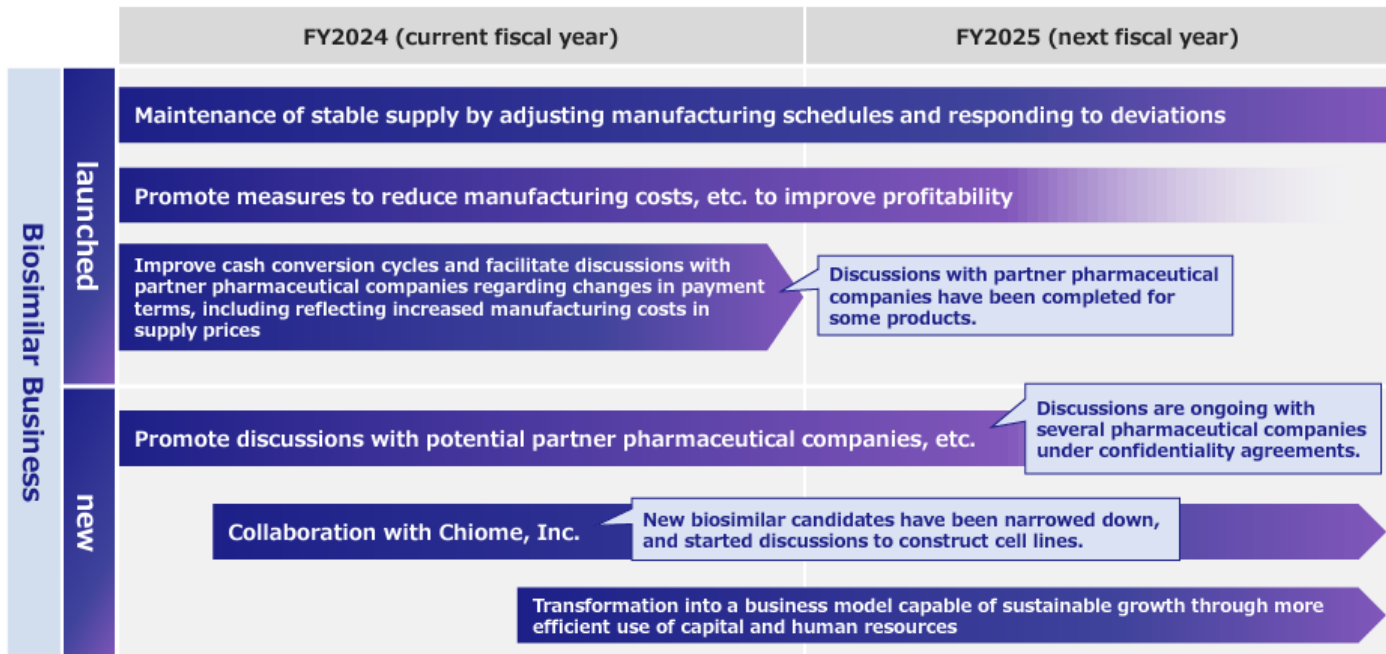
Subject	FY2023	FY2024	
	4Q Result (Non-consolidated)	Full-year Forecast (consolidated)	Progress rate
Net sales	2,431,236	3,500,000 - 4,500,000	+43.9% - +85.0
R&D expenses	1,453,349	1,350,000	--
Operating income ("-" means operating loss)	-1,335,597	--	--
Ordinary income ("-" means ordinary loss)	-1,389,601	--	--
Net income ("-" means net loss)	-1,422,078	--	--

Factors related to the calculation and disclosure of forecast figures for the current fiscal year (ending March 31, 2025)		State of progress
Biosimilar Business (Consultation and coordination with partner pharmaceutical companies and contract manufacturing companies, etc.)	Negotiation of supply prices for biosimilar products to partner pharmaceutical companies in accordance with NHI price revisions, etc.	Partially supported
	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)	Currently supporting
	Coordination of manufacturing and delivery schedules and supply of biosimilar APIs and formulations	Partially supported
	Discussions regarding co-development agreements for new biosimilars	Currently supporting
Cell Therapy Business	Discussions with potential development partners, etc.	Currently supporting

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Source: Omega Investment from company materials

Plans for Major Initiatives -Biosimilar Business (Kidswell Bio)-



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Source: Omega Investment from company materials



Quarterly topics

Plans for Major Initiatives -Cell Therapy Business (S-Quatre)-

		FY2024 (current fiscal year)	FY2025 (next fiscal year)
Cell Therapy Business	first generation	Support for promotion of clinical research on cerebral palsy at Nagoya University	SHED administration and observation in progress.
		Discussions with potential development partners for regenerative medicine products (cerebral palsy)	Contract signing is assumed by the end of FY2024.
		Preparation for IND for cerebral palsy (investigational drug manufacturing, non-clinical studies, PMDA consultation, etc.)	Assuming IND by the end of FY2025.
		Promote research on bone disease indications and develop manufacturing processes for clinical entry	
	next generation	Promote research on gene-modified SHED and other products and develop manufacturing processes toward clinical study	
		New next generation SHED research and research on the use of master cell banks to maximize the value of S-Quatre®	
	*In parallel, prioritize development products according to research data and external environment, and suspend R&D activities for some development products if necessary.		
	Business Structure	Promote external partnerships and funding as S-Quatre® (KWB supports the activity)	Effective April 1, 2024 Cell Therapy Business has been spun-off.
		Search for partners for overseas clinical development, discussion with venture capitalists and contract research organizations, etc.	

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Source: Omega Investment from company materials

Plans for Major Initiatives -Management Strategy (whole group)-

Maximize corporate value, drive stock price recovery and business growth

		FY2024 (current fiscal year)	FY2025 (next fiscal year)
management strategy	(1) Efficient use of management resources	Restructuring of corporate culture and systems	
		Maximize utilization of management resources by improving operational efficiency	Maximize utilization of management resources through further improvements in operational efficiency, etc.
	(2) Optimization of financing methods	Financing according to the nature and stage of each business	By optimizing funding methods and reducing capital requirements by improving capital efficiency, we aim to break away from dependence on the stock market at an early stage. ➢ Although the exercise period of the 10th series of stock acquisition rights has expired, KWB has determined that it is not necessary to raise new funds from the stock market due to the ongoing reduction in the required funds.
		Financing through alliances with development partners, etc.	
	(3) Visualization of business value	Improving the quality of information dissemination to stakeholders	Continuous efforts to "further improve the quality" of information dissemination
		Active dialogue with foreign institutional investors	
		Increased frequency of exposure in the media through more aggressive approaches to the media	

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Source: Omega Investment from company materials

Financial data (quarterly basis)

Unit: million yen	2023/3				2024/3				2025/3
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q
(Income Statement)									
Sales	611	505	611	1,049	46	536	985	864	483
Year-on-year	101.4%	15.5%	-5.0%	464.2%	-92.5%	6.1%	61.3%	-17.6%	950.4%
Cost of Goods Sold (COGS)	293	128	233	597	1	351	352	688	259
Gross Income	318	377	378	453	45	185	633	176	224
Gross Income Margin	52.1%	74.6%	61.8%	43.2%	98.1%	34.5%	64.3%	20.4%	46.3%
SG&A Expense	356	328	524	868	500	449	580	845	383
EBIT (Operating Income)	-38	49	-147	-415	-455	-265	53	-669	-159
Year-on-year	-87.7%	-134.7%	-915.9%	90.4%	1097.7%	-638.6%	-135.9%	60.9%	-65.1%
Operating Income Margin	-6.2%	9.7%	-24.0%	-39.6%	-989.7%	-49.4%	5.3%	-77.3%	-32.9%
EBITDA	-38	49	-146	-415	-455	-264	53	-668	-159
Pretax Income	-81	39	-152	-462	-470	-309	35	-676	-176
Consolidated Net Income	-81	38	-152	-463	-471	-310	33	-675	-177
Minority Interest	0	0	0	0	0	0	0	0	0
Net Income ATOP	-81	38	-152	-463	-471	-310	33	-675	-177
Year-on-year	-74.2%	-125.6%	-141.3%	1.3%	481.4%	-909.1%	-121.6%	45.9%	-62.5%
Net Income Margin	-13.3%	7.6%	-24.9%	-44.1%	-1023.6%	-57.8%	3.3%	-78.0%	-36.6%
(Balance Sheet)									
Cash & Short-Term Investments	1,532	1,875	1,500	1,067	625	622	2,187	2,231	1,167
Total assets	4,305	4,260	4,173	3,895	3,044	3,194	5,199	5,086	4,609
Total Debt	1,700	2,175	2,075	1,950	1,850	1,775	2,275	2,575	2,402
Net Debt	168	300	575	883	1,225	1,153	88	344	1,235
Total liabilities	2,661	2,560	2,485	2,661	2,276	2,119	3,755	4,254	3,895
Total Shareholders' Equity	1,643	1,700	1,688	1,234	769	1,075	1,444	831	714
(Profitability %)									
ROA	-8.12	-3.21	-16.14	-17.85	-28.50	-37.43	-25.82	-31.67	-29.48
ROE	-19.31	-7.05	-34.05	-44.78	-86.81	-100.55	-77.27	-137.73	-152.15
(Per-share) Unit: JPY									
EPS	-2.6	1.2	-4.8	-14.4	-14.7	-9.3	0.9	-17.5	-4.5
BPS	52.3	54.0	52.7	38.5	24.0	30.0	37.6	21.4	18.1
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)	31.44	31.45	31.90	32.06	32.06	37.09	37.31	38.43	39.41

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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