

Kidswell Bio (TYO: 4584)

SHED project progresses well, completing the world's only MCB. Achieved operating profit in 2Q FY2023/3.

◆Summary of results for 2Q FY2023/3

In 2Q FY2023/3, Kidswell Bio's biosimilars (BS) business, including GBS-007, performed well, recording half-year sales of 1 billion yen. In August, Master Cell Bank (MCB) for SHED (Stem cells from Human Exfoliated Deciduous teeth) was completed. Steady progress is also being made in joint research with academia towards practical applications. MCB is a key technological development for the company's future SHED-based business and its completion is expected to accelerate various development activities from 2Q onwards. Against this backdrop, research and development costs were contained up to 2Q, which enabled the company to secure a surplus at the operating profit level. In addition, the continued growth of the biosimilars business is also a factor in the turn to profitability. The company targets sales of 3 billion and operating profit of 1 billion for FY2025 are looking more and more realistic.

◆Stock prices rebounded sharply on the back of good results

The company's share price, which had adjusted sharply since the announcement of full-year results for FY2022/3 in May, rebounded sharply following the publication of research articles on November 7 on the results of research conducted in collaboration with Hamamatsu University School of Medicine. The announcement of the operating profit further boosted the share price. The share price shot up to a limit-high on the 9th, the day after the results were announced. The trading volume on the 10th was 22.9 million shares, an unusually high level in recent years. In addition to completing MCB, the company's project to apply SHED to various diseases has become more concrete, clearing up the project's uncertainty.

◆Results for 2Q of FY2023/3: achieved operating profit

The company's 2Q results for FY2023/3 showed sales of 1,116 million yen, an operating profit of 11 million yen and a net loss of 42 million yen. On a half-year basis sales exceeded 1 billion yen for the first time and the company also achieved a positive operating profit. (In April 2022, the consolidated subsidiary Japan Regenerative Medicine Inc. was transferred to Metcela Inc., so from this financial year the company has been reporting on a parent-only basis.)

In terms of sales, the third BS product, GBS-007, has received more orders than expected since its launch in December 2021, contributing significantly to sales growth. Sales of existing BSs, GBS-001 and GBS-011 also remained strong. In addition, in 2Q, the company recorded revenues from completing SHED's MCB. Furthermore, it appears that milestone revenue from the fourth BS product is also included.

In addition to an increase in gross profit due to growth in the BS business, the company achieved profitability at the operating profit level due to ongoing cost reductions and further curtailment of R&D investment until MCB is completed.

A bank loan of 1 billion yen was taken out at the end of June to secure working capital for the increased orders of GBS-007, with interest paid (13 million yen) and commission paid (30 million yen) recorded as non-operating expenses. Furthermore, a foreign exchange loss (10 million yen) related to the manufacture of active pharmaceutical ingredients overseas was also recorded as a non-operating expense, resulting in a recurring loss of 42 million yen.

2Q results update

Healthcare

As of November 17, 2022

Share price(11/16)	¥292
52 weeks high/low	¥540/200
Avg Vol (3 month)	1,160.1 thou shrs
Market Cap	¥9.1 bn
Enterprise Value	¥9.7 bn
PER (23/3 CE)	-X
PBR (22/3 act)	5.82 X
Dividend Yield (23/3 CE)	-%
ROE (TTM)	-32.17 %
Operating margin (TTM)	-34.10 %
Beta (5Y Monthly)	0.98
Shares Outstanding	31.471 mn shrs
Listed market	TSE Growth

Share price performance



% of	1 mo.	3 mo.	12 mo.
Share prices	34.6%	26.4%	-43.1%
Relative share price	28.8%	27.6%	-40.9%

Points of interest

A drug discovery venture company originated from Hokkaido University. Leading and successful in biosimilars. Focuses on cell therapy (regenerative medicine) using Stem cell from Human Exfoliated Deciduous teeth (SHED) and the development of new biologics.

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

JPY, mn, %	Net sales	YoY %	Oper. profit	YoY %	Ord. profit	YoY %	Profit ATOP	YoY %	EPS (¥)
2019/3	1,021	-3.6	-805	-	-816	-	-856	-	-43.84
2020/3	1,077	-	-1,161	-	-1,187	-	-7,316	-	-264.65
2021/3	996	-7.5	-969	-	-991	-	-1,001	-	-34.79
2022/3	1,569	57.7	-919	-	-952	-	-535	-	-17.35
2023/3 (CE)	2,900	-	-980	-	-999	-	-1,000	-	-31.82
2022/3 2Q*	-	-	-	-	-	-	-	-	-
2023/3 2Q	1,116	-	11	-	-42	-	-42	-	-1.36

* Figures through FY2022/3 are on a consolidated basis. Figures for 1Q FY2023/3 and thereafter are on a non-consolidated basis, and year-on-year comparisons are not shown.

Results for 2Q FY2023/3 (PL)

Unit : thousands yen

Subject	Results for 2Q FY2021 (Consolidated)	FY 2022 ending March 31, 2023 (Non-consolidated)		GAP analysis of forecast in FY 2022
		Result for 2Q	Forecast	
Gross sales	740,635	1,116,111	2,900,000	- Expanding the biosimilar sales led by sales growth of GBS-007 - Recorded the sales related to completion of GMP-compliant SHED MCB
Cost of goods sold	275,700	420,954	1,700,000	
Gross profit	464,935	695,156	1,200,000	Gross profit expansion due to biosimilar business
Selling, general and administrative expenses	915,868	684,018	2,180,000	
R&D expenses	532,689	251,787	1,400,000	Reduced investment in SHED business until confirming the completion of GMP-compliant SHED MCB
Other expenses	383,178	432,230	780,000	Continuously streamlining expenses and recorded expenses as scheduled
Operating profit	-450,932	11,137	-980,000	Recorded operating profit due to reduced R&D investment until confirming the completion of GMP-compliant SHED MCB
Net loss	-463,616	-42,082	-999,000	
Net loss for the quarter	463,221	-42,687	-1,000,000	

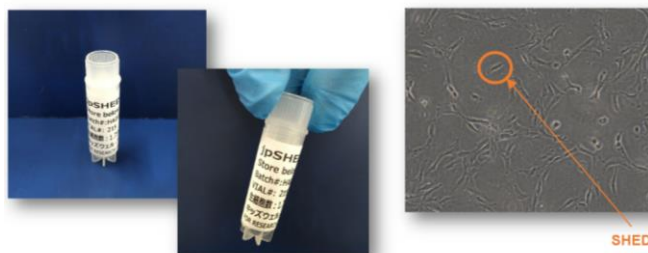
Source: Company materials

On the BS, cash and cash equivalents at the end of 2Q stood at 1.87 billion yen due to the previously reported bank borrowings and the issue of the 4th unsecured convertible bond with stock acquisition rights. Meanwhile, the corresponding non-current liabilities increased to 1.90 billion yen. As a result, total assets at the end of 2Q stood at 4.25 billion yen, an increase of 0.79 billion yen from the end of FY2022/3.

❖**Cell therapy business (regenerative medicine): the SHED MCB is completed. Collaborative research also begins to yield results.**

***MCB completion:** Establishing a stable supply system for the raw materials needed for research and development is an important factor in the practical application of SHED. The company has been working to establish an MCB supply system with ChiVo Net for donor recruitment, university hospitals, Nikon Cell innovation and others to produce the raw materials. The company started the GMP manufacturing required to establish MCB in October 2021 and completed manufacturing MCB in August 2022.

The world's first SHED MCB completed



Frozen SHED MCB in a storage tube*
*Sample

Microscope image of
SHEDs*

Source: Company materials

***Progress in collaboration with academia and companies:** Collaboration with external parties is essential for the commercialisation of SHED. The company has been conducting joint research and other activities with academia and companies. Progress was also made in this area during 2Q (see table below).

Progress in collaboration with academia and others

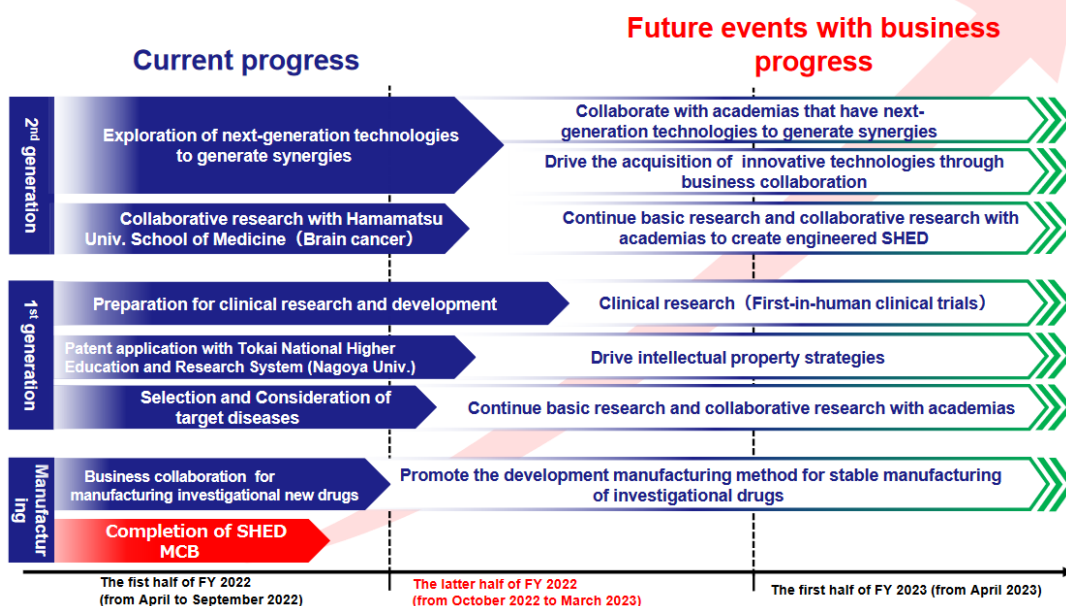
Date of publication	Business partner	Contents
Nov. 7	Dept. of Neurosurgery, Hamamatsu Univ. School of Medicine	High research results confirmed in basic research on novel treatments for brain tumours using second-generation SHEDs. Jointly published research articles.
Oct. 24	Tokai National Higher Education and Research System	In research on the treatment of cerebral palsy, the therapeutic effect of SHED on animal models of the disease was confirmed, and the creation of a candidate therapeutic agent containing SHED was successfully achieved. Signed a joint patent application agreement with Tokai National Higher Education and Research System and applied for a patent for this invention.
Sep. 27	Showa Denko Materials Co., Ltd.	Basic transaction agreement for the development of manufacturing methods and the production of investigational drugs for the practical application of regenerative medicine products that make use of SHED's features.

Source: Company materials



Upgrading the R&D stage with the completion of MCB

- Steady progress in the creation of cell therapy and gene therapy products with SHED
- Timely and appropriate financing for the improvement of corporate value



Source: Company materials

***Business development towards practical application of SHED:** With the completion of MCB, the company's SHED business has made significant progress. See the diagram above for future stages of research and development. By collaborating with academia and others, the company will consider early practical applications in first-generation SHED, followed by designer cell applications in second-generation SHED. Furthermore, beyond that, the use of SHED for other modalities through the provision of SHED will be considered.

***New COO position:** As an R&D-based drug discovery venture, Masayuki Kawakami has led basic research and exploration as CTO at the company. To expand the SHED business and promote clinical development and product strategy with a greater awareness of commercialisation, the management executive structure has been strengthened. Thus, Mr. Kawakami has been appointed to the newly created position of Chief Operating Officer (COO). He will be responsible for translating basic research into clinical development and commercialisation.

Executive Officer, Chief Operating Officer (COO) : Masayuki Kawakami



Personal history :

Kyoto Univ. Graduate School of Engineering, Ph.D
Worked for research laboratories of FUJIFILM Corp. mainly in oncology area with Harvard Univ. and Novartis (then Sandoz). Worked for Toyama Chemical Corp. and then for FUJIFILM Pharmaceuticals USA to promote an anti-influenza drug clinical development. Joined the company in 2017; appointed Executive Officer CTO in 2018 and Executive Officer COO in 2022.

***Reinforcement of IP strategy:** As a drug discovery venture company, the company has been formulating and promoting R&D and business development strategies. As the SHED business expands, the company plans to focus on IP strategies in conjunction with R&D and business development strategies. Strategic patent applications and patent lifecycle management are promoted. In addition to domestic patent applications, the company will also promote the acquisition of patents in Europe, the US and major Asian countries. Specifically, the company intends to promote its IP strategy by filing 'substance (cell) patents' to differentiate SHED from other cells, 'use patents' to secure rights for the treatment of target diseases, and 'formulation' and 'administration method' patents to extend the patent term.



❖ Biosimilars business: better-than-expected sales of GBS-007

***Ranibizumab (GBS-007):** On December 9, 2021, the third product in the BS business, ranibizumab BS, an anti-VEGF antibody drug for age-related macular degeneration, was launched by development partner Senju Pharmaceutical. The BS has attracted a lot of attention as it is the first BS in the ophthalmology field, and sales have been strong, with orders exceeding initial forecasts. As previously reported, the company has raised funds to support increased production.

***Filgrastim (GBS-001):** GBS-001 have already been launched by the partner company, and cost-reduction measures have also been taken to improve profitability. It is reported that Mochida Pharmaceutical has decided to discontinue sales of GBS-001, but it is explained that this will not affect the company's forecasts for the current financial year or its medium-term management plan.

❖ New biologics business: joint research agreement with Chiome Bioscience

***Collaborative research with Chiome Bioscience:** The company has positioned the new biologics business as part of its key future growth strategy. However, as developing new bio drugs requires a vast amount of research resources, joint research with other companies that are strong in their respective fields of expertise is effective. In June, the company announced an alliance with Chiome Bioscience (TYO: 4583), which has strengths in the field of antibody drugs.

◇ Forecast for FY2023/3: Initial guidance unchanged, but operating loss may be less than forecast.

The forecast for FY2023/3 of sales of 2.9 billion yen, an operating loss of 0.98 billion yen and a net loss of 1 billion yen remains unchanged from the initial forecast. Sales up to 2Q are less than 40% of the full-year forecast, but the company target looks achievable as sales of GBS-007 and other BSs are expected to remain strong. Meanwhile, the company has set its full-year forecast for R&D expenditure at 1.4 billion yen and expects an operating loss of 980 million yen. However, up to 2Q, R&D expenditure was 250 million yen, and even considering that R&D expenditure is heavily weighted towards the second half of the year, it is difficult to imagine the company spending 1 billion yen or more in the second half of the year. It is highly likely that the full-year operating loss will be smaller than the company guidance.

Pipeline Updates

Cell therapy (Regenerative Medicine) Business

Development Product	Target	Basic Research	Non-Clinical and Clinical Trial	Conditional & Time-limited Authorization	Marketing/ Marketing Authorization/ Continuous Production	Partner
1st Generation SHED	Cerebral palsy					Nagoya University, Tokyo Medical and Dental University
	Congenital Isolated Hypoganglionosis					Mochida Pharmaceutical
	Spinal cord injury					Nagoya University
	Non-union fractures					Hokkaido University and Spinal Injuries Center
2nd generation SHED	Brain Cancer					Hamamatsu Univ. School of Medicine
	Under consideration					NanoCarrier and BioMimetics Sympathies

Biosimilar Business

Development Product	Target	Development Research	Clinical Trial		Application	Launch	Partner
			Phase I	Phase III			
GBS-001 GBS-007 GBS-011	Oncology Ophthalmic disease Renal disease						Fuji Pharma Senju Pharmaceutical Sanwa Kagaku Kenkyusho
4th BS Product		(※Non-disclosure)					
5th BS Product thereafter	Under consideration						

New Biologics Business

Development Product	Target	Basic Research	Non-Clinical Trial	Clinical Trial			Application/ Approval/ Launch	Partners
				Phase I	Phase II	Phase III		
New Antibody	Oncology							Sapporo Medical Univ. Chiome Bioscience Inc. MabGenesi

Source: Company materials



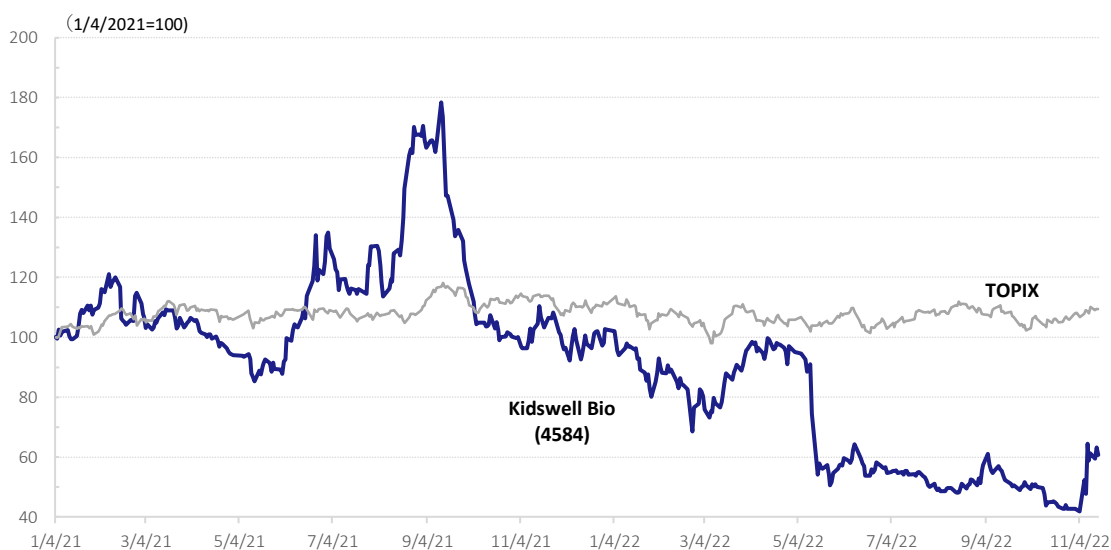
◇ Stock price: rebounding on good results and progress of SHED.

The company's share price has adjusted significantly since the announcement in May of its financial results for FY2022/3 when it announced the postponement of achieving profitability in FY2023/3. However, the share price rebounded sharply following the publication of a paper on November 7 on the results of research conducted in collaboration with Hamamatsu University School of Medicine. The announcement of an operating surplus further boosted the share price performance. The share price shot up to a limit-high on the 9th, the day after the results were announced. The trading volume on the 10th was 22.9 million shares, an unusually high level in recent years. In addition to the completion of MCB, the company's project to apply SHED to various diseases has become more concrete, clearing up uncertainty regarding the project. The company's share price is worth a close watch.

Stock price transition (last 6 years)



Relative share price (4584, TOPIX)



Financial data

FY (¥mn)	2020/3				2021/3				2022/3				2023/3	
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
[Statements of income]														
Net sales	284	30	419	345	121	53	547	276	303	438	642	186	610	505
Cost of sales	77	8	359	209	5	35	46	34	122	154	183	91	292	128
Gross profit	207	22	60	136	116	19	500	242	182	283	460	94	318	377
SG&A expenses	417	423	381	365	354	463	465	565	491	425	442	580	356	328
R&D expenses	235	249	201	213	138	265	198	363	297	236	237	380	105	147
Operating profit (loss)	-210	-401	-321	-229	-238	-445	36	-323	-309	-142	18	-486	-37	49
Non-operating income	0	0	1	0	0	1	1	1	2	0	0	1	0	3
Non-operating expenses	2	1	20	4	7	5	4	8	6	8	15	7	43	13
Ordinary profit (loss)	-212	-402	-340	-233	-244	-450	33	-330	-314	-150	4	-493	-80	39
Extraordinary income	4	0	0	2							418	0	-	-
Extraordinary expenses	5,939	0	0	194	0	1	8	0					-	-
Profit (loss) before income taxes	-6,147	-402	-340	-425	-244	-451	26	-331	-314	-148	421	-493	-80	39
Total income taxes	1	0	3	-2	1	0	0	1	0	1	52	-51	0	1
Net profit (loss)	-6,147	-403	-342	-424	-245	-451	25	-330	-314	-149	369	-441	-80	38
[Balance Sheets]														
Current assets	2,761	2,390	3,238	3,322	3,573	3,218	3,329	3,346	2,794	3,203	3,722	3,326	4,079	4,035
Cash equivalents and short-term securities	1,654	1,602	2,482	2,033	2,658	2,502	1,830	1,461	874	974	1,253	1,187	1,532	1,874
Non-current assets	330	427	418	270	379	393	340	588	728	656	178	177	225	224
Tangible assets	2	2	2	2	2	2	2	3	3	2	2	2	1	1
Investments and other assets	328	425	416	268	374	389	336	582	722	651	173	173	220	220
Total assets	3,091	2,817	3,656	3,592	3,952	3,611	3,670	3,934	3,522	3,859	3,901	3,503	4,304	4,259
Current liabilities	421	550	529	881	772	858	925	1,114	823	1,034	1,045	1,129	1,175	651
Short-term borrowings	25	25	25	25	25									
Long-term debts to be repaid within one year												75	250	300
Non-current liabilities	25	24	1,224	1,224	1,384	1,287	1,231	1,209	1,051	826	718	656	1,485	1,908
Long-term debt			1,200	1,200	1,340	1,240	1,200	1,100	900	700	700	625	1,450	1,875
Long-term borrowing			600	600	600	600	600	600	600	600	600	525	1,350	1,275
Convertible bonds			600	600	740	640	600	500	300	100	100	100	100	
Total liabilities	446	573	1,752	2,105	2,156	2,145	2,156	2,324	1,873	1,860	1,763	1,785	2,661	2,560
Total net assets	2,644	2,244	1,904	1,487	1,796	1,466	1,514	1,610	1,648	1,999	2,138	1,719	1,643	1,699
Total shareholders' equity	2,644	2,244	1,904	1,487	1,796	1,466	1,514	1,610	1,648	1,999	2,138	1,719	1,444	1,500
Capital	612	612	612	612	842	892	912	1,032	1,150	1,420	1,420	1,421	1,424	1,433
Legal capital reserve	9,917	9,917	9,917	9,917	10,147	10,197	10,217	10,338	10,456	10,725	10,726	10,727	10,730	10,739
Retained earnings	-7,908	-8,311	-8,653	-9,077	-9,322	-9,773	-9,748	-10,079	-10,393	-10,542	-10,173	-10,614	-10,710	-10,672
Stock acquisition right	38	43	51	57	70	82	101	116	134	145	165	185	199	199
Total liabilities and net assets	3,091	2,817	3,656	3,592	3,952	3,611	3,670	3,934	3,522	3,859	3,901	3,503	4,304	4,259
[Statements of cash flows]														
Cash flow from operating activities		-604		-1,325		-104		-1,267		-857		-1,169		-709
Loss before income taxes		-6,548		-7,314		-695		-999		-462		-533		-42
Cash flow from investing activities		-106		-137		-5		-22		-		526		-23
Expenditure on acquisition of intangible/leased assets		-		-		-3		-3		-		-1		-
Purchase of investment securities		-100		-100		-		-		-		-		-50
Sales of investment securities		-		-		-		-		-		526		-
Cash flow from financing activities		40		1,221		579		718		370		369		1,446
Income from the issuance of convertible bond-type bonds with stock acquisition rights														970
Income from issuance of shares by exercising stock acquisition rights		-		599		599		599		-		-		499
Income from issuance of stock acquisition rights		40		40		-		138		370		369		-
Proceeds from issuance of new shares		-		3		4		4		-		-		-
Net increase in cash and cash equiv.		-670		-240		468		-571		-486		-273		713
Cash and cash equiv. at beginning of period		2,009		2,009		2,032		2,032		1,461		1,462		1,160
Cash and cash equiv. at end of period		1,602		2,032		2,501		1,461		974		1,187		1,874

Note: Consolidated basis until FY2022/3; non-consolidated basis from 1Q FY2023/3. For the statement of cash flows, the figures for 2Q are the cumulative figures for the period from 1Q to 2Q, and the figures for 4Q are the cumulative figures for the period from 1Q to 4Q. Therefore, the opening balance is also the balance at the beginning of each quarter.

Source: Omega Investment from company materials



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