Kidswell.Bio

Financial Results for FY 2022
(Fiscal Year Ended March 31, 2023)

May 12, 2023

Biotech Striving for Value Creation
– For a Comprehensive Healthcare System for Children, Families, and Society –

Kidswell Bio Corporation

Business Highlights in FY2022 (1)

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Cell Therapy (Regenerative Medicine) Business

- Established SEHD drug discovery platform based on S-Quatre® with the completion of GMP-compliant SHED MCB.
- Accumulating data of SHED basic research by promoting in-house and collaborative research with academia.
- Making a great progress of initiatives on the start of clinical research/ trials for the first generation SHED.
- Driving initiatives for maximizing the value of SHED drug discovery platform
  (Research of the second generation SHED, pursuit of synergies with other modalities and preparation for the business activities in the U.S.)

SHED Drug Discovery Platform

S-Quatre®

GMP-compliant
SHED MCB

First Generation (Naive SHED)

Starting the preparation for clinical research/ clinical trial

- Clinical research on cerebral palsy, one of the target diseases of the first generation SHED, was confirmed by Certified Regenerative Medicine Committee of Nagoya University
- Clinical research/ clinical trials for other disease are under preparation of clinical research/ clinical trials

Second Generation (Reinforced SHED)

- Identified enhancement methods and target diseases through collaborative research with academia.
- Driving R&D activities for starting US business development
- Preparing a new research organization for accelerating research activities

Other Modalities and Synergies

Preparing a new research system to create new seeds utilizing SHED as a row material

Business Highlights in FY 2022 (2)

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Biosimilar (BS) Business

- **Promoting the development of new biosimilars while maintaining stable revenue (supply) from existing BS products**
- **Prioritizing manufacturing cost reduction**

GBS-001
Filgrastim BS
(Approved in Nov. 2012)

- Biosimilar of G-CSF preparation filgrastim for neutropenia, etc. Alfa Biosimilar

富士製薬工業

GBS-011
Darbepoetin alfa BS
(Approved in Sept. 2019)

- Biosimilar of continuous Erythropoiesis Stimulating Factor Preparation Darbepoetin alfa

SKK 株式会社 三和化学研究所

GBS-007
Ranibizumab BS
(Approved in Sept. 2021)

- Biosimilar of anti-VEGF antibody drug ranibizumab
- **Strong sales and more orders than expected**
- **Approved of additional indication (diabetic macular oedema)**

SENJU "見える"の向こうにあるものを。 千寿製薬株式会社

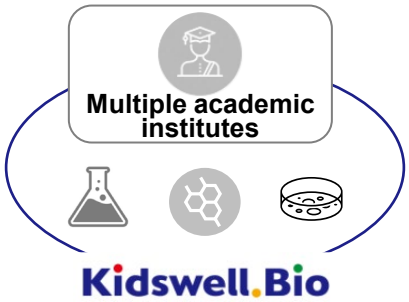
Fourth BS Product
(Under development)

Non-disclosure

New Biologics Business (Antibody drugs)

- **Promoting to discover antibody drugs with new mechanisms**

Preclinical and clinical data



A patent grant for anti-RAMP2 antibodies

New mechanism which inhibits the formation of new blood vessels with a new mechanism.

Collaborative Research

Financial Results in FY 2022 (PL): Income Statement

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Unit：thousands yen

Subject	Results for 4Q FY2021 Consolidated	FY2022 ended March 31, 2023 (Non-consolidated) Results for 4Q	Year-on-year ratio	Highlights	Forecast	Progress rate
Gross sales	**1,569,233**	**2,776,241**	**177%**	• **Expanded the biosimilar sales led by sales growth of GBS-007.** • **Recorded the sales related to completion of GMP-compliant SHED MCB.** • **Although there was a delay of shipment of some products, the sales were generally in line with the original plan.**	**2,900,000**	**96%**
Cost of goods sold	550,357	**1,250,553**	227%		1,700,000	74%
(Cost of sales ratio)	35%	45%			59%	
Gross profit	**1,018,875**	**1,525,688**	**150%**	• **Gross profit expansion due to strong sales in biosimilar business.**	**1,200,000**	**127%**
Selling, general and administrative expenses	1,937,994	**2,076,617**	107%	R&D expenses • Less R&D expenses of GBS-007 and JRM-001 due to stock transfer. • More investment in cell therapy business. Other selling, general and administrative expenses • Increased payment of royalty due to strong sales in biosimilar business. • Continuously streamlining expenses.	2,180,000	95%
(Cost of sales ratio)	123%	75%			75%	
R&D expenses	1,150,210	**1,216,349**	106%		1,400,000	87%
(Cost of sales ratio)	73%	44%			48%	
Other expenses	787,784	**860,268**	109%		780,000	110%
Operating loss	**-919,119**	**-550,929**	**--**	• **Despite increased payment of royalty due to strong sales in biosimilar business, operating loss decreased through prioritizing investments and continuous cost reduction.** • **Full-year forecast also significantly decreased losses.**	**-980,000**	**--**
Net loss	-952,640	-624,769	--		-999,000	--
Net loss for the year	**-535,259**	**-657,434**	**--**	• **This fiscal year's net income (loss) increased due to recording the income from sale of investment securities as extraordinary income in the FY 2021 but is expected to improve significantly compared with the full-year forecast.**	**-1,000,000**	**--**

- **Well business in the biosimilars and steady progress in the cell therapy business such as preparation for clinical research of SHED pipeline.**
- **Net sales increased. Profit improved at each profit stage, except for quarterly net income, which was due to special factors in the previous fiscal year.**
- **Steadily taking a step forward to achieve the numerical targets of the Medium-Term Strategic Plan (KWB2.0).**

Financial Results in FY 2022: Balance Sheet

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(Unit：thousand yen)

Subject	4Q FY 2021 Non-Consolidated	4Q FY2022 Non-Consolidated	Highlights
Current assets	3,294,940	3,697,155	
(Cash and cash equivalents)	1,160,934	1,067,162	✓ Cash increased due to long-term loan from Mizuho Bank and the issuance of the 4th series of CBs.
(Trade receivables)	461,854	1,088,766	✓ Due to strong sales growth of GBS-007
(Products)	200,118	213,007	
(In-process inventory)	788,696	422,308	
(Advance payments)	495,544	821,536	
(Long-term debts to be repaid within one year from a subsidiary)	600,000	–	
(Other current assets)	161,537	84,373	
(Allowance for doubtful accounts)	-573,745	–	
Non-current assets	175,396	197,609	
Total assets	**3,470,336**	**3,894,765**	
Current liabilities	1,111,168	1,055,839	
Non-current liabilities	656,260	1,605,420	✓ Due to long-term loan from Mizuho Bank and the issuance of the 4th series of CBs, etc.
Total liabilities	1,767,428	2,661,259	
Total shareholders' equity	1,702,908	1,233,505	
Total liabilities and shareholders' equity	**3,470,336**	**3,894,765**	

- **The net asset ratio has been reduced due to long term loan and issuance of CBs, but the level of liquidity has been kept.**
- **Accelerating investment in cell therapy business with increased liquidity and operating cash flow from biosimilars.**

Forecast of FY 2023

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- **Expecting to achieve sales target of KWB 2.0 two years ahead of schedule due to strong sales of GBS-007 and revenue from the fourth BS product.**
- **Continuing to invest in SHED cell therapy businesses infrastructure as well as pipelines.**
- **In addition to the increase of R&D expenses, the COGS ratio will temporarily increase due to changes in the product mix.**
- **Expecting to achieve the KWB 2.0 by contributing to profits by further expansion of sales of the biosimilar business in FY2025, while continuing to invest in the cell therapy business.**

(Unit: thousand yen)

Subject	Results in FY 2022	Forecast for FY2023	Increase/ decrease ratio
Gross sales	**2,776,241**	**3,500,000**	**+26.1%**
R&D expenses	1,216,349	1,600,000	+31.7%
Operating loss	**-550,929**	**-1,500,000**	**--**
Net loss	-624,769	-1,550,000	--
Net loss for the year	**-657,434**	**-1,550,000**	**--**

Accelerating our R&D activities to realize our vision for patients who are waiting for new medical treatments

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Steadily proceeding with the preparation for clinical research / clinical trial

SHED MCB Completed

Establishment of revenue base

Establishment of biosimilar development technology

- Acquisition of biopharmaceutical development know-how
- Strong sales of GBS-007
- Started development of the fourth BS product
- New BS pipeline development

Accelerating cell therapy products development

Focusing on SHED development

- Accelerating development overseas in addition to domestic development
- Active investment in human resources and capital
- Accelerating R&D by fund-raising from overseas investors and public research funds such as AMED

Launching cellular medicine / cell therapy products

Aiming to launch the world's first SHED medicine / therapy by FY2030

- Steady development progress in Japan and overseas
- Strengthening SHED business activities
- Diverse personnel structure, including experts in cell medicine development and human resources with knowledge of new modalities

SHED + Human Resource Development

Maintaining stable revenue of biosimilar business

Founding (2001) to FY2021 | FY2022 | FY2025 (3 billion yen of sales and 1 billion yen of operating profit) | FY2030 onward

Financing measures appropriate for each business development stages

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To improve pipeline value, a variety of financing methods has been/will be taken at the right time, and our financing policy continues.

FY2019–

Acquisition of Advanced Cell Technology and Engineering Ltd.
= Financing after starting a full-scale regenerative medicine business

Financing measures	Purpose
Cash: about 1 billion yen/year	Fixed expenses, R&D expenses (Basic research of antibody drugs and SHED)
Long-term debt: 1.6 billion yen	Working capital for Biosimilar (BS) business and a part of development capital
CB and warrants: 2.2 billion yen	• Development of manufacturing process for GBS-007 and fourth BS product • Completion of SHED MCB and development of cell culture process

FY2023–

Financing measures (Scheduled)	Purpose
Cash: about 1 billion yen/year	Fixed expenses and basic research of SHED
Unexercised warrants (issued): about 600 million yen	Responding to BS production expansion
Long-term debt	Order expiation of GBS-007 and working capital after launching the fourth BS product
Stock issue and subsidy (AMED, etc.)	Clinical research, preparation for starting clinical trial and enhancing manufacturing system

FY2025–

Financing strategies

- SHED Clinical Development: In addition to stock procurement and collaboration with partners (companies and investment funds), subsidies from AMED, etc. will be applied according to the progress of the pipeline development.
- Apply debts such as long-term debt from banks considering business profits

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Steady progress in delivering SHED products (treatment methods) to patients

KWB2.0

- Accumulating data of SHED basic research
- Identifying indications
- Completion of SHED MCB
- Established a drug discovery platform based on S-Quatre®

- Clinical research led by academia
- Manufacturing SHED MCB compliant with the U.S. FDA requirements
- Development of mass culture methods

KWB3.0

- Corporate trials (Ph1/ 2a, Cerebral palsy, etc.)
- Alliances with development partners
- Establishment of manufacturing methods of final products

Launch SHED products

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Under preparation for clinical research (first-in-human)

Completion of SHED MCB in Aug. 2022 (S-Quatre®)

Publication of the third research article in collaboration with Hamamatsu University School of Medicine in Nov. 2022(Second generation of SHED)

Patent application on cell therapy for cerebral palsy utilizing SHED with Tokai National Higher Education and Research System in Oct. 2022 (First generation of SHED)

Approved the clinical research plan of Nagoya Univ. in Feb. 2023 (First generation SHED)





FY2022 FY2023 FY2025 FY2030 Onward

Outlook for FY2023

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New Facility		
Tokyo Laboratory	Opening of a new laboratory in Tokyo to accelerate research on the second generation SHED (reinforced SHED)	
Management Structure	Strengthen management structure for overseas business expansion	
Cell Therapy (Regenerative Medicine) Business		
First generation SHED (Naïve SHED)	Cerebral palsy	Starting a clinical research led by Nagoya Univ. Preparing for industry-sponsored trials in Japan
	Congenital Isolated Hypoganglionosis	Starting a clinical research led by academia or Investigator-initiated trials
	Optic nerve disease	Promoting collaborative research with new partners Preparing for corporate clinical trail in the U.S.
Second generation SHED (Reinforced SHED)	Brain cancer	Collaborative research (Hamamatsu Univ. School of Medicine)
	Spinal cord injury	Collaborative research（Nagoya Univ.）
Other modalities and synergies	Discussion with several potential partners for alliances	
SHED manufacturing	Manufacturing SHED master cell bank (MCB) compliant with the U.S. FDA requirements	
Biosimilar Business		
Fourth BS product	Under development	
Fifth BS product and etc.	Identifying development candidates and starting selecting partner companies	

Establishment of R&D system for maximizing the value of SHED

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Accelerating R&D activities aiming at launch of SHED products in Japan and the U.S. with agile research activities by Sapporo and Tokyo laboratory

Tokyo Headquarter

Under preparation for starting clinical trials in the U.S.

Making New Innovations by Implementing SHED R&D Strategies

Sapporo Laboratory

NEW

Tokyo Laboratory

SHED Basic Research/ functional elucidation

- Continuing SHED basic research and development research including manufacturing process development
- Continuing collaborative research with existing academia and partners
- Continuing existing research of the second generation SHED

Sharing and accumulating research know-how and connection

Advanced research of the second generation SHED

- Pursuing new and unique science with advanced technologies.
- New generation of SHED and collaborative research with new partners/ academia
- Creating new modalities/ technologies utilizing SHED (maximizing the value of S-Quatre®)

Pipeline Highlight of Cell Therapy (Regenerative Medicine)

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Development Product	Target disease	Development Stage*1				Partners	Number of Patients※2	
		Research Target	Research	Preclinical	Clinical		Domestic	Global
First Generation SHED	Cerebral palsy					**Nagoya University, Tokyo Medical and Dental University**	**2,000 patients per year, (30,000 patients in total)**	**125,000 participants (under 10 years old)**
	Congenital Isolated Hypoganglionosis					Mochida Pharmaceutical	100 participants	—
	Spinal cord injury					Nagoya University	5,000 patients per year, (100,000 patients in total)	13,000 cases per year
	Ophthalmologic disease, etc.					Gifu Pharmaceutical University	*3	*3
	Non-union fractures					Hokkaido University	100,000 patients per year	—
	Cleft lip and palate					ORTHOREBIRTH	2,000 patients per year	15 out of 10,000 newborns
Second Generation SHED	Brain cancer					Hamamatsu University School of Medicine	20,000 patients per year	27,000 parents per year
	Spinal cord injury					Nagoya University	5,000 patients per year, (100,000 patients in total)	13,000 cases per year
	Neurodegenerative disease, etc.							
Other Modalities	Autoallergic disease, etc.							
	Exosomes and mitochondria, etc.							

*1【Our development stage definitions: Preclinical indicates pharmaceutical development and preliminary toxicity studies for clinical trials, Research indicates acquired animal POC, Research Target indicates before acquisition of animal POC, *2 Internal research based on Global Data, Global Cancer Observatory, *3 Details not disclosed*

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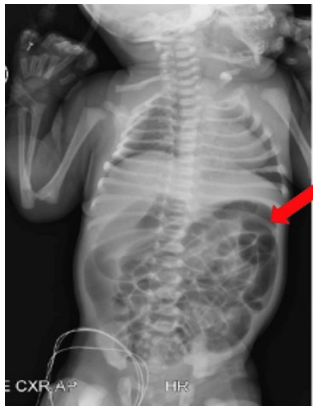
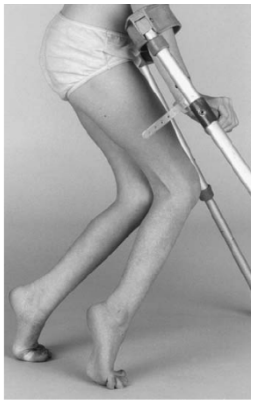
Delivering SHED regenerative medicine products for diseases for which effective treatment methods have not yet been established

Congenital Isolated Hypoganglionosis



(DOI: 10.7759/cureus.33680)

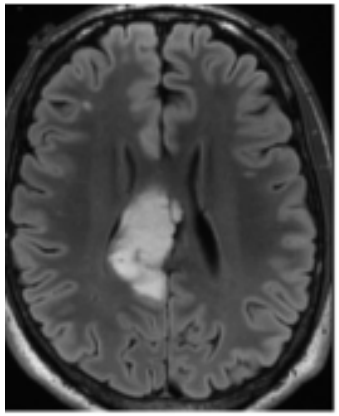
Cerebral palsy



(DOI:10.1302/0301-620X.85B2.14066)

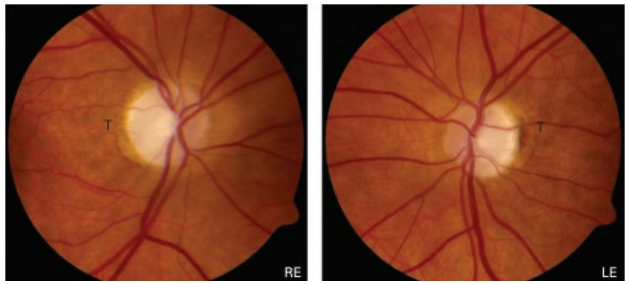
(FOUNDATION PARALYSIE CEREBRALE "White Paper on cerebral palsy")

Brain Cancer



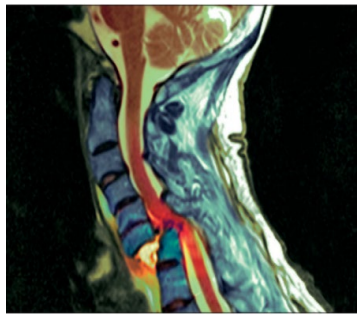
(DOI: 10.3390/cancers11010111)

Ophthalmologic disease



(doi:10.1136/jmg.2007.054270)

Spinal cord injury



(DOI:https://doi.org/10.1016/S1474-4422(09)70162-0)

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All for Kids, Kids for All

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Cautionary Statement

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This material includes information on pharmaceutical products and regenerative medicine (or related products), etc., which is being developed or launched. However, this is not intended to promote our products or provide medical advice.