



## Financial Results for 3Q FY 2023

(Fiscal Year Ending March 31, 2024)

**February 7, 2024** 

## **Biotech Striving for Value Creation**

For a Comprehensive Healthcare System for Children,Families, and Society –

## **Kidswell Bio Corporation**



- **♦** Financial Highlights in the 3Q FY2023
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## Financial Highlights in the 3Q FY2023

### Financial Results in 3Q FY 2023 (PL): Income Statement



Unit: thousands yen

Subject	Results for 3Q FY2022	FY2023 ending March 31, 2024			
		Results for 3Q	Year-on- year ratio	Forecast	Progress rate
Gross sales	1,726,862	1,566,742	91%	3,500,000	45%
Cost of goods sold	654,042	703,808	108%		
Gross profit	1,072,819	862,934	80%		
Selling, general and administrative expenses	1,208,342	1,529,959	127%		
R&D expenses	579,055	807,465	139%	1,600,000	50%
Other expenses	629,287	722,493	115%		
Operating loss	-135,523	-667,025		-1,500,000	
Net loss	-194,023	-712,858		-1,550,000	
Net loss for the quarter	-194,930	-747,400		-1,550,000	

- Due to adjustments in the manufacturing schedule of some biosimilar products, delivery scheduled for the current fiscal year may be
  delayed to next fiscal year. Currently under investigation with CMOs, but if the delivery date is delayed to the next fiscal year ,strong
  demand will be a positive factor for next year's sales.
- GBS-010 (Pegfilgrastim biosimilar), which was launched in November 2023, will have a limited contribution to sales this fiscal year. It is expected to grow significantly from next fiscal year onward

### Financial Results in 3Q FY 2023: Balance Sheet



Unit: thousands yen

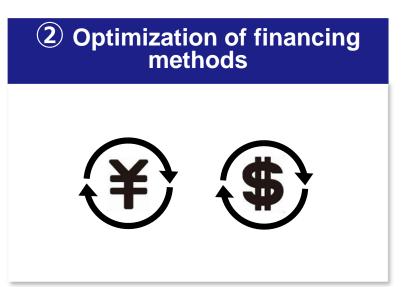
Subject	4Q FY2022	3Q FY2023
Current assets	3,697,155	5,036,812
(Cash and cash equivalents)	1,067,162	2,186,682
(Trade receivables)	1,088,766	481,855
(Products)	213,007	187,960
(In-process inventory)	422,308	1,149,405
(Advance payments)	821,536	819,463
(Other current assets)	84,373	211,444
Non-current assets	197,609	161,723
Total assets	3,894,765	5,198,535
Current liabilities	1,055,839	1,988,383
Non-current liabilities	1,605,420	1,766,610
Total liabilities	2,661,259	3,754,993
Total shareholders' equity	1,233,505	1,443,541
Total liabilities and shareholders' equity	3,894,765	5,198,535

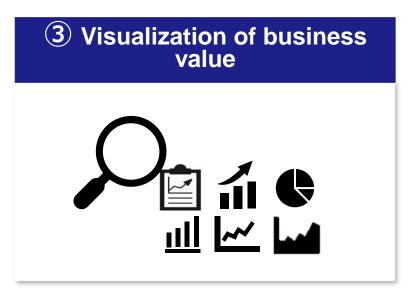
- Cash and cash equivalents balance was improved due to additional bank loan from Mizuho Bank.
- Based on the strong sales performance of each biosimilar product, working capital for manufacturing keeps high level to ensure future stable supply. Continue to coordinate with partner companies to improve capital efficiency.

## Strategies for Maximizing Corporate Value









Maximizing corporate value, realizing stock price recovery and improvement

## **1** Concentration of management resource



### **Business progress by the end of 2023**

#### **New Biologics Business**

 Patent applications have been completed for some projects based on research results.

#### **Biosimilars Business**

- Launched four BS products through collaborative development with partner companies.
- Started discussions with potential partner companies regarding the 5<sup>th</sup> BS product, etc.

#### **Cell Therapy Business**

- Started clinical development with the first generation SHED.
- Research is progressing on the secondgeneration SHED, etc.

#### **Selection and Concentration**

- For accelerating efficiently utilization of management resources and improvement in business value, management resources (human resources, funds) will be concentratedly invested in the following two businesses instead of three businesses (biosimilars, new biologics, and cell therapy) that were previously dispersed.
  - Biosimilars business as a stable revenue base business
  - > Cell therapy business where progress in R&D activities is more noticeable as a growth business
- New biologics business will focus on business development activities for collaboration and alliances with external companies.

### 2 Optimization of financing methods 3 Visualization of business value



- By making the biosimilars business and the cell therapy business separate companies, KWB expects to
  - carry out financing measures according to the characteristics of each business,
  - > improve the "visualization of business value" by disclosing the performance of each business.
- The new company plans to carry out its own flexible financing, including partner companies and venture capital (Diversification of Financing Methods).

	KWB	S-Quatre Corporation
Core business	Biosimilars business	Cell therapy business (SEHD R&D)
Business characteristics	Middle-risk and middle-return	High-risk and high-return
Position of business (Business stage) Strategies Financing methods (usage of financing)	Revenue base business (Return stage)  Expanding profitability from sales of launched BS products and new product development  Debt financing (for manufacturing)	Growth business (Upfront investment stage) Pioneer benefits from upfront investment in advanced modalities  Equity financing (for SHED R&D activities)
Major IR events	<ul> <li>Expand profits of launched four products</li> <li>Conclude contracts with partner companies on new BS products</li> </ul>	<ul> <li>Progress in clinical development of the first generation SHED</li> <li>Conclude contract with partner companies</li> <li>Progress in clinical development of the second generation SHED</li> </ul>

## **Biosimilars Business Updates**



#### Accelerate further growth while focusing on maximizing profits from launched products

#### For growth of launched products after FY2024

#### Strategies for increased demand

- For responding to the steady increase in demand, KWB will continue to expand the manufacturing capacity of CMOs (partially completed)
- Based on forecasts from partner companies, KWB is adjusting the production schedule in and after the next fiscal year. (partially completed)
- Continue discussions with financial institutions on additional financing to meet the increase in manufacturing working capital

#### For further growth of the biosimilar business

#### Consideration of the development of 5<sup>th</sup> biosimilar product, etc.

- Actively promoting the development of new biosimilars considering national policies to promote the use of biosimilars
  - Completed selection of development of highly profitable BS
  - Under discussions with several potential collaborative development partners.

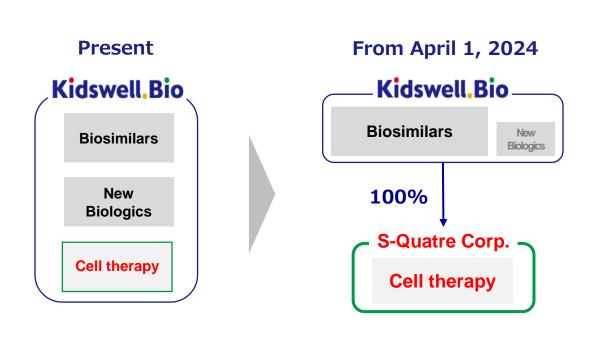
## **Cell Therapy Business Updates**

- Establishment plan of S-Quatre Corporation -

### Outline of establishment plan of the new company



- The cell therapy business using stem cells from human exfoliated deciduous teeth (SHED), which R&D activity is driven as a future growth business, will be separated from KWB and succeeded to the new company, S-Quatre Corporation.
- The new company was named S-Quatre Corporation because its core business is research and development of SHED utilizing SHED stable supply platform "S-Quatre®"
- Will be established as a 100 % subsidiary of KWB on April 1, 2024.



Outline of the new company		
Company name	S-Quatre Corporation	
Location	1-2-12, Shinkawa, Chuo-ku, Tokyo, 104-0033, Japan	
Scheduled establishment	April 1, 2024	
Amount of capital	5,000 thousand yen	
CEO Board of Directors Auditor	Yasuyuki Mitani Masayuki Kawakami, Shinya Kurebayashi Osamu Sugawara	
Core business	Cell therapy (SHED-based R&D)	

### S-Quatre: SHED business plan



For maximizing the value of S-Quatre®, S-Quatre will flexibly promote collaboration with partner companies, secure external funds and aim to accelerate the development of SHED.

#### **Major R&D activities**

**First generation SHED Clinical development** 



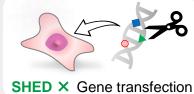


**Expanding the use of SHED in a** variety of modalities





**Second generation SHED** To the next stage



Overseas expansion of SHED business with S-Quatre<sup>®</sup> in compliance with U.S. FDA



Implementation of own unique financing

- Financing through collaboration at the early stage with partner companies and venture capitalists (Starting industry-sponsored clinical study)
- Acquisition of public funds by strengthening collaboration with academia (Development of investigator-led clinical study)

### SHED Development Status (Cerebral palsy)



#### **Autologous** SHED

- Manufacture of SHED from the patient's own baby teeth
- Administered to the patient and confirmed safety

#### Approved by **Establishment of** Committee for **Clinical research (Nagoya Univ.)** manufacturing and Regenerative administration methods Medicine Under enrollment of the cases FY2023 (Present) **Completed a part of PMDA consultation** Phase I/IIa Complete examination of Trial Manufa Completion of establishment of S-Quatre manufacturing cturing manufacturing methods **Completion of MCB manufacturing** (GMP) Aiming to apply for in a GMP facility of clinical trial materials clinical trials by the end Completed **Toxicity** of FY2025 preliminary testing toxicity (GLP) testing

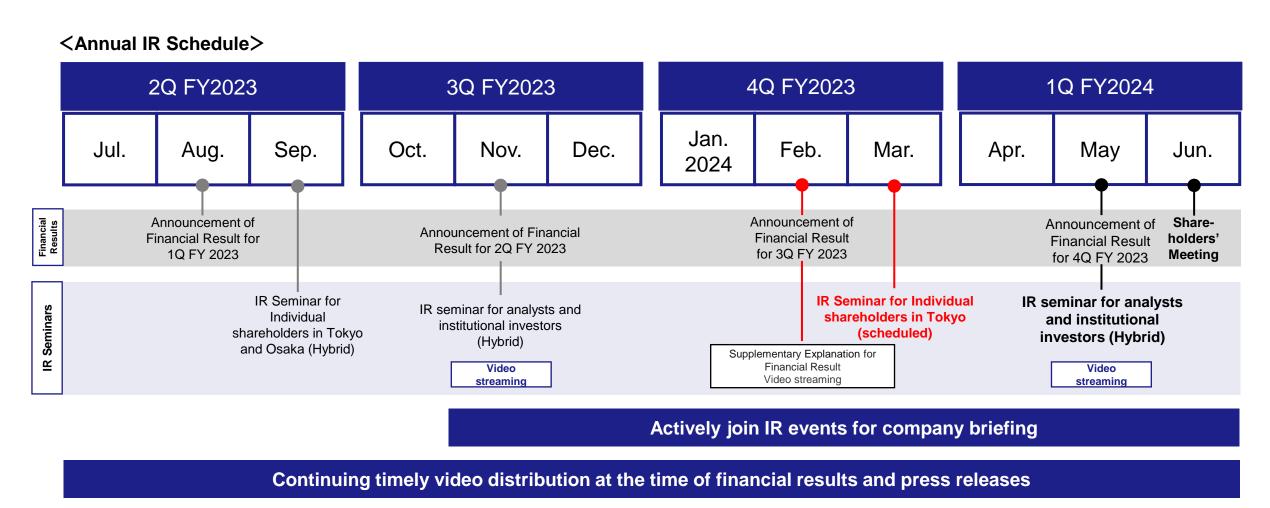
#### **Allogenic SHED**

- SHED from healthy donors
- Can be administrated to many patients and confirming the effectiveness and safety.

## IR Strategies



#### Basic IR Policy: Increase opportunities for dialogue with the stock market and investors





# KIDS WELL, ALL WELL

All for Kids, Kids for All





### **Cautionary Statement**



This information material is provided for understanding Kidswell Bio Corporation ("KWB"), not for soliciting investment in KWB shares.

Information provided in this material may contain so-called "forward-looking statements." These statements are based on current expectations, forecasts, and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Risks and uncertainties include success rate of R&D projects, new regulations and rules, relations with partners in the future, etc.

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.

## **Appendix**



## Yasuyuki Mitani, PhD CEO, S-Quatre Corporation (scheduled on Apr 1, 2024)

1996	BS, Pharmaceutical Science, Kyoto University. Obtained a license for pharmacist.
1998	MS, Biophysics, Graduate School of Pharmaceutical Sciences, Kyoto University.  Joined Astellas Pharma (f/k/a Fujisawa Pharmaceutical). Mainly engaged in the drug discovery research for neurodegenerative and muscle diseases until 2019.
2013	PhD, Neuropharmacology, Graduate School of Pharmaceutical Sciences, The University of Tokyo.
2015	Postdoctoral Research Fellow, Cincinnati Children's Hospital Medical Center (US). Engaged in the research of stem cell transplantation for pediatric diseases.
2017	Visiting Scientist, Buck Institute for Research on Aging (US). Engaged in the research of cell aging.
2019	Joined Kidwell Bio Corporation (f/k/a Gene Techno Science Co., Ltd.) as Manager in Research & Development Dept. Initiated and led multiple collaborative researches with academia to build pipelines of SHED (Stem cells from Human Exfoliated Deciduous teeth).
2020	Deputy Director, Business Development Dept.
2021	Director, Business Development Dept. and Regenerative Medicine Unit Leader, Product & Portfolio Strategy.
2023	Chief Scientific Officer.