

# Financial Results for FY 2021 (Fiscal Year Ended March 31, 2022) May 12, 2022

**Kidswell Bio Corporation** 

# Cautionary Statement Kidswell, Bio

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 "forwardlooking 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 advices.

# Business and Financial Highlights in FY 2021

# Overview of Financial and Business Highlights Kidswell, Bio

#### **Financial Highlights**

#### Financial Highlights in FY 2021

- ✓ Full-year sales increased by biosimilar due to the addition of GBS-007. Revenues related to MCB completion shifted to FY 2022
- ✓ Gross profit for the full year exceeded the forecast due to the contribution of biosimilar
- ✓ R & D expenses are about 650 million yen less than scheduled due to partnering of JRM and biosimilar development period shifted to FY 2022, etc.
- ✓ No impact on business performance due to the COVID-19 pandemic

Business Highligh	ts
Biosimilar	<ul> <li>GBS-007: Received Approval Manufacturing and Sales in Japan and launched in Dec. 2021.</li> </ul>
Regenerative medicine (Cell Therapy )	<ul> <li>Executed a business alliance agreement with Metcela Inc. in the regenerative medicine field</li> <li>Executed a development agreement on "designer cell", the 2<sup>nd</sup> generation cell therapy, with BioMimetics Sympathies Inc.(BMS)</li> <li>Executed a collaborative research agreement with NanoCarrier Co., Ltd.</li> <li>Started manufacturing master cell bank (MCB) in compliance with GMP → Completed</li> <li>Executed a share purchase agreement with Metcela Inc. (Development of JRM-001 is led by Metcela, Inc.)</li> </ul>
Others	<ul> <li>Recorded extraordinary income (sales profit of investment securities) in accordance with about 500 million yen cash proceed.</li> <li>Due to the transfer of a subsidiary (JRM), the company will shift to non-consolidated financial statements from 1Q FY 2022 ending March 2023.</li> </ul>

# Consolidated Financial Results in FY 2021 (PL) Kidswell, Bio

Consolidated income statement Unit : thousands yer					
	Results for	FY2021			
Subject	3Q/FY 2020	Results for 4Q/FY 2021	Forecast	GAP analysis of forecast in FY 2021	
Gross sales	996,543	1,569,232	1,900,000	<ul> <li>✓ Profits from GBS-001 and GBS-011 exceeded the forecasts</li> <li>✓ Included sales of GBS-007</li> <li>✓ Sales of APIs related to the API manufacturing process development for the 4th BS product are partly included in the budget due to a change of the development plan (No impact on the development schedule).</li> <li>✓ Sales related to the completion of the MCB will be shifted to FY 2022.</li> </ul>	
Cost of goods sold	119,571	550,357	1,020,000	<ul> <li>✓ Recorded 96 million yen for MCB completion as cost of development in 1Q FY 2021 (It is a reserve for loss on orders according to the accounting method.)</li> <li>✓ Full-year forecasts include the temporary cost of about 650 million yen as the cost of the manufacturing process establishment for the 4th biosimilar product and related to the completion of the MCB → Related to the completion of the MCB will be shifted to FY 2022.</li> </ul>	
Gross profit	876,971	1,018,875	880,000	<ul> <li>✓ Gross profit recorded higher than expected due to a stable bioshimilar profit</li> </ul>	
Selling, general and administrative expenses	1,846,659	1,937,994	2,600,000		
R&D expenses	963,868	1,150,209	1,800,000	<ul> <li>✓ Flexible revision of development costs by reviewing development plans</li> <li>✓ Revisions of development expenses related to JRM-001 due to transfer of subsidiary (JRM)</li> <li>✓ Costs related to GBS-007 cost reduction measures are partly shifted to FY 2022.</li> </ul>	
Other expenses	882,791	787,784	800,000	$\checkmark$ Continuously streamlining selling, general and administrative expenses	
Operating profit	-969,687	-919,118	-1,720,000		

Note: Net loss attributable to owners of parent was -535,000 thousand yen (full-year forecast : 1,323,000 thousand yen) due to extraordinary income (gain on sale of investment securities) in 3Q/FY2021.

### Consolidated Financial Results for FY 2021 (BS)

#### **Consolidated balance sheet**

Unit : thousands yen

Subject	FY2020	FY2021	Highlight
Current assets	3,346,310	3,325,939	
(Cash and cash equivalents)	1,461,158	1,187,189	<ul> <li>✓ Revenue from the sale of investment securities was generated, but investment in R&amp;D continues.</li> </ul>
(Trade receivables)	816,737	461,854	<ul> <li>Expecting increase in FY 2022 onward due to the sales of GBS-007</li> </ul>
(Products)	70,712	200,118	
(In-process inventory)	380,039	788,696	
(Advance payments)	431,718	495,544	
(Other current assets)	185,943	192,536	
Non-current assets	587,641	177,396	✓ Decrease due to investment securities sold
Total assets	3,933,952	3,503,335	
Current liabilities	1,114,319	1,128,562	
Non-current liabilities	1,209,246	656,260	✓ Decrease due to conversion of convertible bonds
Total liabilities	2,323,566	1,784,822	
Shareholders' equity	1,610,385	1,718,513	
Total liabilities and shareholders' equity	3,933,952	3,503,335	

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### **Financial Forecasts for FY 2022**

**Financial Forecast** 

Unit : thousands yen

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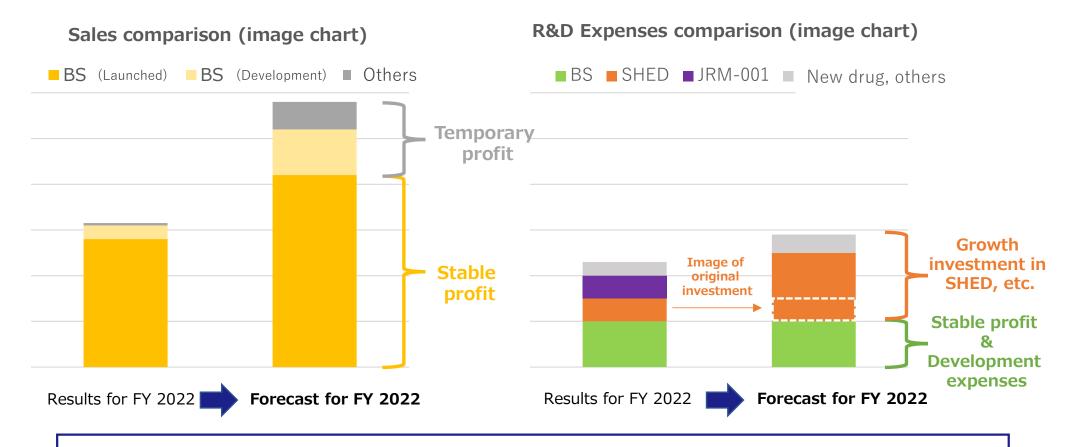
Subject	Results for FY 2021	Forecasts for FY 2022	Highlight
Gross sales	1,569,232	2,900,000	<ul> <li>The sales of GBS-001 will decrease compared to FY 2021 due to inventory adjustments of the sales company</li> <li>Significant growth due to full-year sales of GBS-007</li> <li>Temporary revenue from completion of MCB in compliance with GMP</li> <li>Including sales of the APIs related to development of manufacturing process for the fourth biosimilar product and development milestone</li> </ul>
Cost of goods sold	550,357	1,700,000<	<ul> <li>✓ Including sales related to increase in the sales of GBS-007</li> <li>✓ Including temporary cost due to the completion of MCB manufacturing in compliance with GMP</li> <li>✓ Including the temporary cost of the manufacturing process establishment for the 4th biosimilar product</li> </ul>
Gross profit	1,018,875	1,200,000	
Selling, general and administrative expenses	1,937,994	2,180,000	
R&D expense	1,150,209	1,400,000	<ul> <li>More growth investment in SHED pipelines (Action plans for acceleration of SHED pipelines and overseas expansion)</li> <li>✓ For licensing-out, additional investments in establishing a high-volume culture system of SHED based on positive nonclinical results</li> <li>✓ Development expenses for efficient company-led clinical trials</li> <li>✓ Additional investment in manufacturing for the long-term stable supply of GBS-007</li> <li>✓ Development expenses for cost reduction measures of GBS-007</li> </ul>
Other expenses	787,784	780,000	$\checkmark$ Continuously streamlining selling, general and administrative expenses
Operating profit	-919,118	-980,000	

#### Continuing growth investment based on a stable profit structure of biosimilar business

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**Business forecast** 

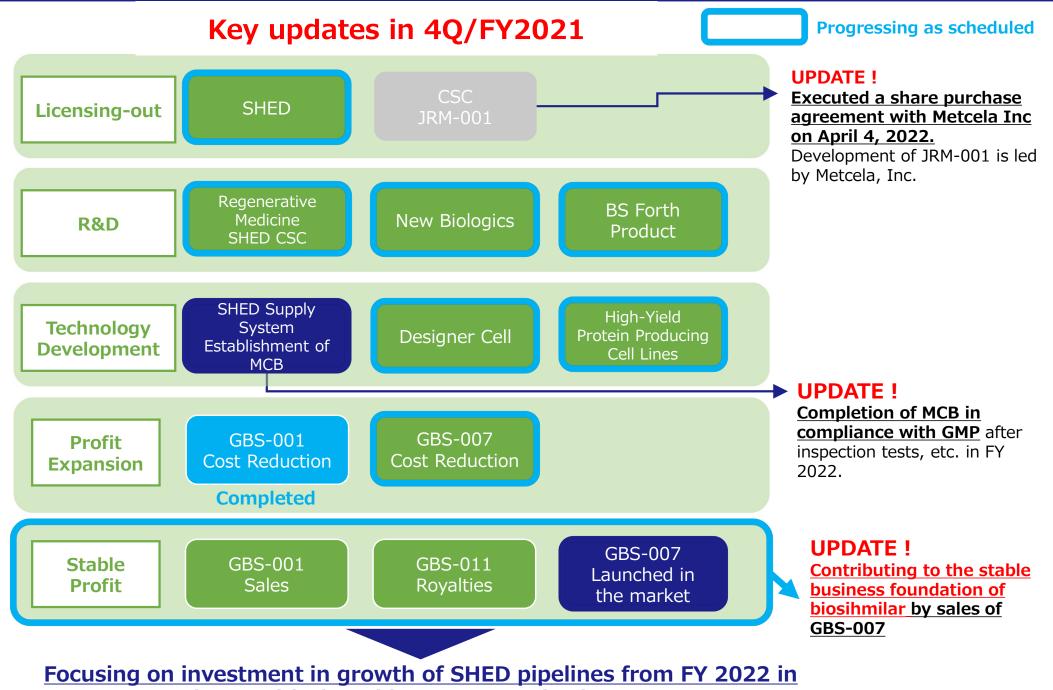
#### Sales increased with the addition of GBS-007 R&D strategy shifts to focusing on growth investment while securing biosimilar-led structure for expanding and stabilizing profit



Though having a profit structure enabling us to achieve break-even by keeping the scale of original growth investment in SHED, etc., KWB aims to expand future growth investment and further enhance corporate value.

### **Key Updates in Mid-Term Strategic Plan**

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accordance with the mid-term strategic plan KWB 2.0



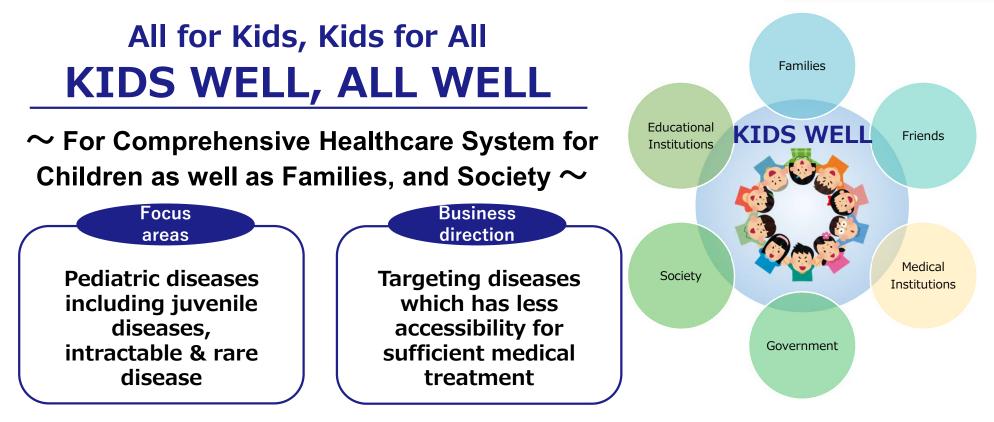
# Mid-Term Strategic Plan KWB 2.0 Part-1

# All for Kids, Kids for All **KIDS WELL, ALL WELL**

# **Kidswell Bio Corporation**

\*Details for SHED, biosimilar and new biologics pipelines will follow as Part-2.

# **Our vision**



#### All for Kids, Kids for All

- Under the declining birthrate and aging population, reducing the burden on children is a major social issue.
- Provide new pharmaceuticals and therapeutics to patients suffering from diseases and contribute to the realization of a society where children and adults who support children live happily and brightly.

Mid-term strategic plan KWB 2.0 to survive in the competitive environment and promptly realize our vision



## **Reasons for launching KWB 2.0**

- Changes in the biosimilar market -

- Launched GBS-007,our third biosimilar product, as the first biosimilar in the ophthalmology field in Dec. 2021.
  - > Sales continue to be better than expected and expecting further growth
- <u>The entry of biosame (authorized biosimilar (AGS)) into the market is getting impacts</u> to the biosimilar market

**Competitive Biosame** 

Name of product	Indications	Medicinal effects	Development Company	Approval date	Impact on KWB's products
Eylea (Aflibercept)	Age-related macular degeneration	Anti-VEGF antibody drugs	Bayer Yakuhin, Ltd.	Feb. 2022	Competitive product of GBS- 007
Nesp (Darbepoetin Alfa)	Renal anemia	Erythropoietin Receptor Activator	Kyowa Kirin Co., Ltd.	Aug. 2018	Competitive product of GBS- 011

- As the number of biosame entering the market will increase, the competition for market share with biosimilars will intensify (profitability will decline). As a result, potential partners of pharmaceutical companies will hesitate to launch new biosimilar projects.
- > Biosimilar projects that secure enough profitability will become less.
- Continue to maximize value for existing biosimilar pipelines
- Need to change KWB's profit structure that relies solely on biosimilar businesses.

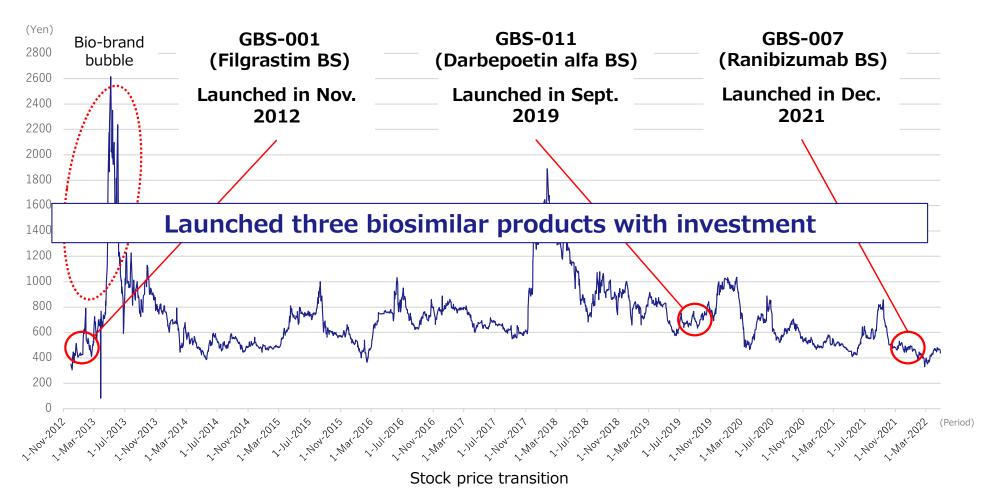
#### Accelerating the creation of new medicines to increase corporate value by SHED (cell therapy) development

### **Reasons for launching KWB 2.0**

-Strategies for an increase in stock prices -

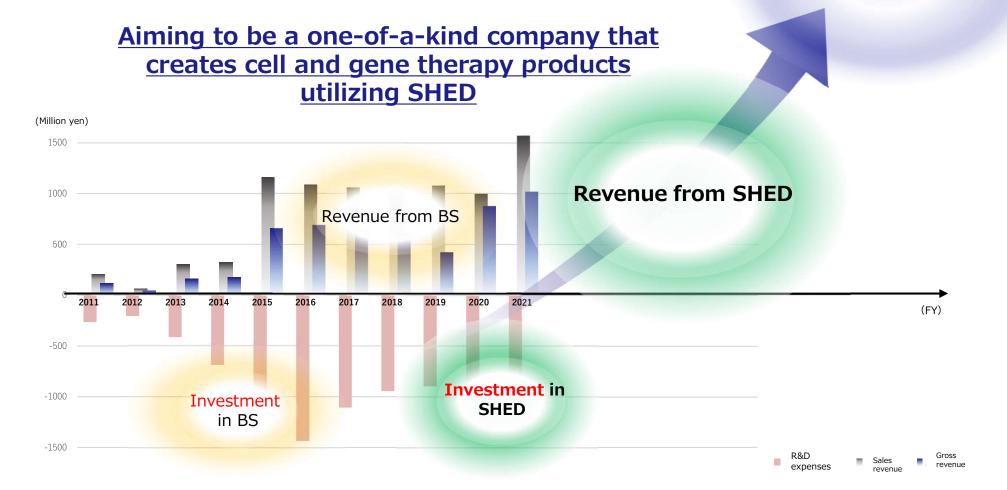
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#### The stock market didn't evaluate KWB's business expansion by launching biosimilars.



- The launch of biosimilars alone didn't lead to stock price increase.
- Sticking to achieving target profitability with the biosimilar business alone won't be reflected in "big" stock price increase.

- Aiming to launch the world's first SHED medicine/ therapy products by FY 2030 **Enhancing corporate**
- Continue biosimilar business and new biologics business



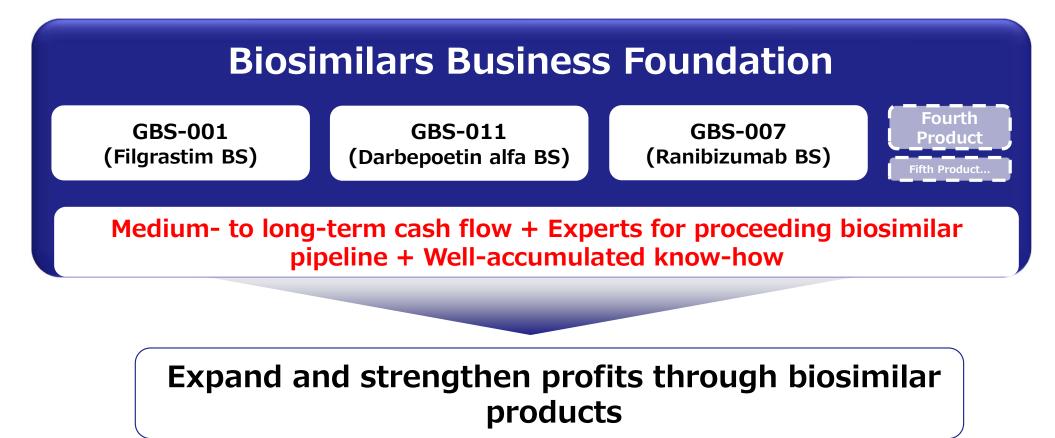
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value

### **Business foundation for KWB 2.0**

### **Step-ahead strengths among other bio ventures**

- Profit structure achieving sales of 3 billion yen and operating income of 1 billion yen in FY 2025
- Well-knowledge and experienced human resources in biologics development
- Well-accumulated know-how in the development of biosimilar products



# Growth strategies for breakthrough in SHED Kidswell, Bio

Technology

#### Commercialization

Launching regenerative medicine products of the 1<sup>st</sup> generation of SHED



For Launching regenerative medicine products of the 1st generation of SHED

- Establishment of SHED Supply system
- Selection of target diseases through collaborative researches
- Establishment of clinical development system

Invention in SHED and next generation technology

For commercialization of the 2<sup>nd</sup> generation of SHED

- Introduction of next-generation technologies to generate synergies
- Combination with synergistic devices
- Promoting technology adoption through alliances and acquisitions

# Focusing on R&D of SHED pipelines and accelerating R&D in Japan and overseas

**Fund-raising** 

Financing for strategic execution Human resources and organizational structure

Strengthening SHED development structure

- Financing from overseas market
- Large-scale financing to realize SHED commercialization
- Equity financing specialized for SHED development

- Establishment of a SHED delivery system to overseas
- Establishing office in overseas
  - Fostering networks with international medical institutions and academia
  - Strengthening cooperation between Japan and overseas
- Staff recruiting for global expansion

# Breakthrough in SHED

- Prompt commercialization of the first generation of SHED -

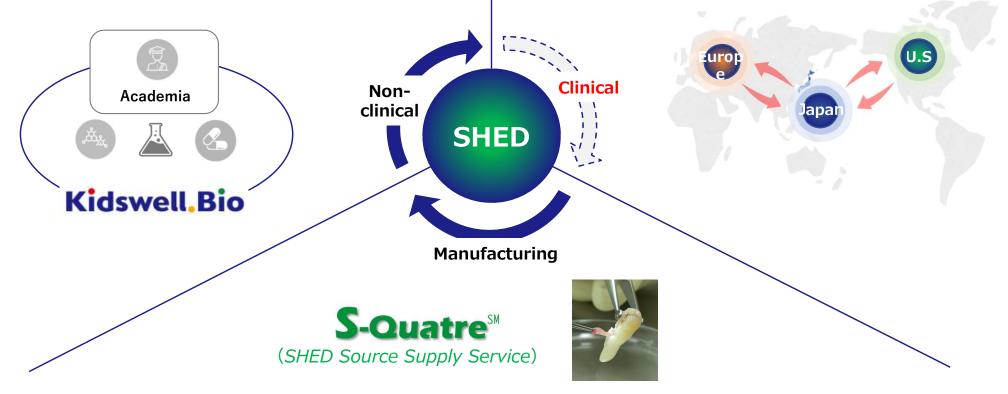
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# Selecting target diseases through joint research with academia

Based on the evidence through our R&D, further joint research will be promoted and maximize SHED potential.

#### Accelerating clinical development in Japan and overseas

Through Real World Data (RWD), Virtual Clinical Trials (DCT), aiming for shortened clinical trial period and early commercialization



A one-stop service to providing highly reliable and domestically produced SHED as an intermediate product for regenerative medicine products through business collaboration

# Focusing on SHED development and accelerating investment for increase in corporate value

		Estimation
	Non-clinical study to ~ Corporate clinical trial (Expansion of indications)	2 to 5 billion yen
Japan	Recruiting, development of human resource and organizational framework	Some hundreds million yen
	2022 — 2030 —_→(year)	
Over	Feasibility studyCollaborative researchCorporate clinicaltrial	2 to 5 billion yen
seas	<ul> <li>Office in overseas, recruiting &amp; fostering global staff, the development of organizational structure</li> <li>Introduction of next-generation technologies with synergies (Corporate alliances, M&amp;A)</li> <li>Promoting the development of the next generation of SHED</li> </ul>	Over 5 billion yen
	Required investment in SHED development	Over 10 billion yen

Making investments for launching SHED regenerative medicine/ cell therapy products with equity financing

# Strategic Investment in human resources and organizational structure

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- Contributing to society by the development of human resources and organizational structure that leads to an increase in KWB's corporate value
- Pursuing contributions to society (S in sustainable development goals) through the creation of new medical treatments

#### **Experts**

- Recruiting human resources with knowledge and experience in the regenerative medicine (cell therapy) field
- Recruiting human resources with knowledge of next-generation modality
- Recruiting global human resources for overseas business activities

#### **Challenging work environment**

- Talent management to realize human resources strategy
- Fostering a corporate culture with diversity (gender, age, nationality, values)
- Flexible and appropriate personnel allocation
- Execution of career development plan (human resources development plan)

#### Respect for each employees' work style

- Flexible work system under emergency and pandemic
- Establishing work infrastructure for flexible work styles
- Fostering a corporate culture for understanding each working style

Organizational culture with plenty of creativity and innovation



# Roadmap

#### Accelerating our R&D activities to realize our vision

- Accelerate SHED R&D activities to realize our vision and increase corporate value.
- Continue stable revenue from biosimilar business and reduce manufacturing costs
- Determine when to achieve profitability by prioritizing accelerated investment

#### Establishment of revenue base

#### Establishment of biosimilar development technology

- Acquisition of biopharmaceutical development know-how
- Stable revenue from three BS products
- Started development of the 4<sup>th</sup> BS product
- New BS pipeline development

Founded (2001) to FY 2021

### Accelerating cell therapy products development

#### Focusing on SHED development

- Accelerating development in overseas. in addition to domestic development
- Active investment in human resources and capital
- Accelerating R&D by fund-raising from overseas investors

### **KIDS WELL, ALL WELL**

Launching cellular medicine /cell therapy products

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

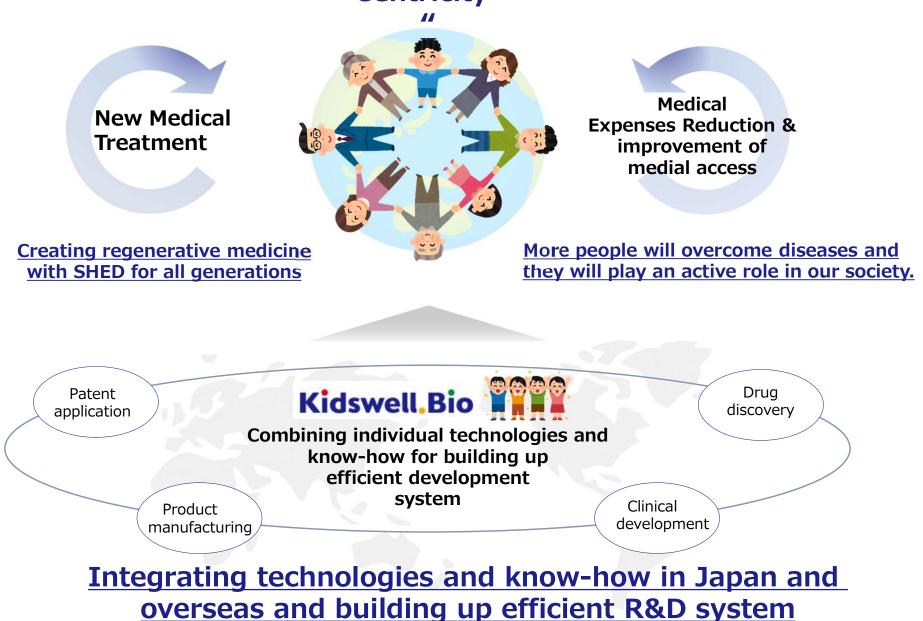
- Steady development progress in Japan and overseas
- Establishment of SHED platform
- Strengthening SHED business activities
- Diverse personnel structure, including experts of cell medicine development and human resources with knowledge of new modalities
- SHED + Human Resource Development

Maintaining stable revenue of biosimilar business

FY 2022

**FY 2025 (Turning profitable)** (3 billion yen of sales and 1 billion yen of operating profit ) FY 2030 onward

#### Two Virtuous Cycles through "Kids Centricity"



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