



## Financial Results for 2Q/FY2021 (Fiscal Year Ending March 31, 2022)

## November 5, 2021

**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.

# Kidswell Bio Corporation (кwb)

Kids+wellness All for KIDS, KIDS for All

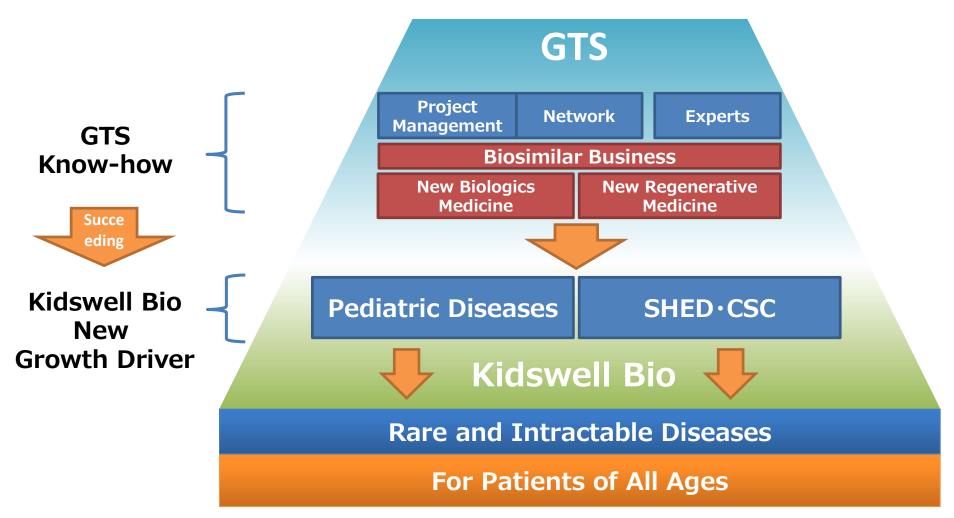
## **Biotech Engineering Company, Striving for Value Creation**

For a comprehensive healthcare system for children as well as families and society

Made a new start as Kidswell Bio Corporation, or KWB, from July 1, 2021. Under "Kids Well, All Well", we will make our goal come true.

#### From GTS to Kidswell Bio

Create and deliver a new medical care for patients of all ages who is suffering from rare and intractable diseases by leveraging pediatric diseases and new modality perspective



## Business and Financial Highlights in 2Q/FY2021

Financial Highlights

#### Financial Highlights in 2Q/FY2021

- $\checkmark$  Sales results were in line with the forecast.
- $\checkmark$  R&D is steadily proceeding.
- ✓ No impact on business performance due to the COVID-19 pandemic.

#### **Business Highlights**

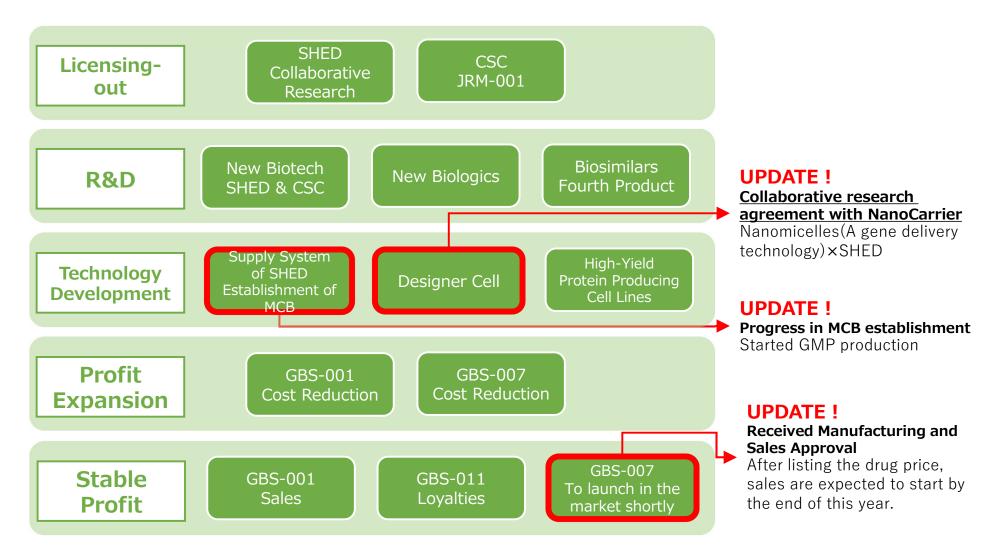
Biosimilar	<ul> <li>GBS-007: Received Manufacturing and Sales Approval for biosimilar in the Ophthalmic Area in Japan.</li> </ul>
New Biotech (Regenerative medicine/ Cell Therapy)	<ul> <li>Collaborative research agreement with NanoCarrier Co., Ltd. for development of a designer cell as reinforced cell therapy utilizing SHED.</li> <li>Started GMP production of Master Cell Bank (MCB).</li> </ul>

Unit : thousands yen

Subject	Results for 2Q/FY2020	Forecasts f	or FY2021	Highlights	
Subject		Results for 2Q/FY2021	Forecasts		
Gross sales	174,487	740,635	1,900,000	<ul> <li>✓ Included profits from GBS-001 and GBS-011.</li> <li>✓ Recorded drug substance sales related to the manufacturing process for the 4th biosimilar product</li> </ul>	
Cost of goods sold	39,964	275,700	1,020,000	<ul> <li>✓ Included 96 million yen for MCB completion in cost of sales as budgeted (It is a reserve for loss on orders according to the accounting method.)</li> </ul>	
Gross profit	134,523	464,935	880,000		
Selling, general and administrativ e expenses	817,249	915,868	2,600,000		
R&D expense	403,208	532,689	1,800,000	<ul> <li>✓ Although R&amp;D expense increased from the previous term, it was due to carrying over of R&amp;D expenses into FY2021. The final stage of commercial manufacturing of GBS-007 is smoothly proceeding.</li> </ul>	
Other expenses	414,040	383,178	800,000	<ul> <li>✓ Continuously streamlining Selling, General and Administrative expenses</li> </ul>	
Operating profit	-682,725	-450,932	-1,720,000		

## Updates of Mid-Term Strategic Plan From FY2021 to FY2025





## GBS-007: Expansion of BS portfolio for profitability **Kidswell.Bio**

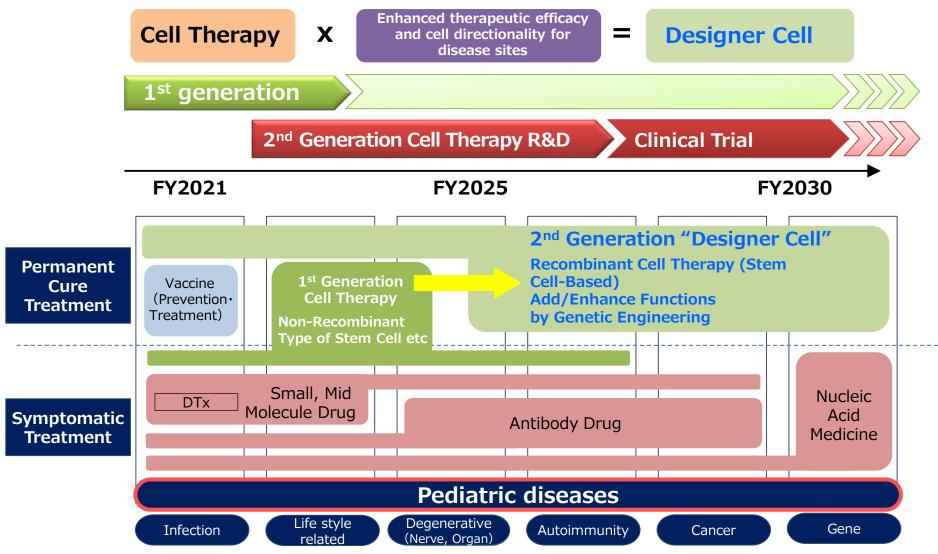
Highlights					
<ul> <li>✓ Launching the third product of biosimilars to the market.</li> <li>✓ After listing the drug price, sales are expected to start by the end of this year. Partially contributed to our sales this fiscal year.</li> <li>✓ Providing new options for patients as the first BS in the field of ophthalmology.</li> </ul>					
■ Outline	Biosimilar of Anti-VEGF antibody drug Ranibizumab as a medicine for age-related macular degeneration				
Target disease Age-related macular degeneration	A disease in which waste products accumulate in the macula, which controls eyesight in the eyeball, or new blood vessels form in the macula with aging, making it difficult to see				
Development Partner Senju Pharmaceutical Co., Ltd.	One of the leading domestic companies in the field of ophthalmology, which handles a wide range of medical drugs for ophthalmology and otolaryngology.				
Market of Anti-VEGF antibody drug	Targeting the domestic market for existing treatments for age-relatedmacular degenerationLucentisAbout 27 billion yen (Domestic, FY2020)EyleaAbout 65 billion yen (Domestic, FY2020)				
■ Outlook	Sales will start from this fiscal year with approval. The indications for this drug are only a part of the preceding products. Additional indications will be added accordingly. Actively promoting not only domestic but also overseas expansion, which has a larger market.				

#### UPDATE

#### Showed positive effectiveness of non-clinical studies in SHED pipelines Accelerating licensing-out activities to pharmaceutical companies

	Target disease	symptom	Existing Treatment	Therapeutic target	Partners	Number of patients (Domestic)	Number of patients (Global)
Pediatric disease	Cleft lip and palate	Eating and speech disorder	Lip arthroplasty + iliac bone graft	Maxilla bone regeneration	ORTHOREBIRTH	2,000 patients per year	15 out of 10,000 newborns
Pediatric disease	Congenital Isolated Hypoganglionosis	Intestinal obstruction	Enterectomy, colostomy	Ganglion regeneration	Mochida Pharmaceutical	100 patients	-
Pediatric disease	Cerebral palsy	Quadriplegia and Posture disorder	None	Nerve protection, activation and regeneration	Tokyo Metropolitan Institute of Medical Science, Nagoya University, Tokyo Medical and Dental University	2,000 patients per year, 30,000 patients in total	100,000 patients per year, 1.7 millions patients in total
Including Pediatric disease	Spinal cord injury	Loss of motor function and sensation	None	Nerve protection, activation and regeneration	Nagoya University	5,000 patients per year, 100,000 patients in total	25,000 patients per year, 500,000 patients in total (US, EU and Japan)
	Non-union fractures	Chronic pain, gait disturbance	Surgery	Bone regeneration	Hokkaido University and Spinal Injuries Center	100,000 patients per year	-
	Peripheral nerve palsy	Motor function and sensation disorder	Nerve reconstruction (Autologous nerve transplantation)	Peripheral nerve regeneration	Oita University	8,000 surgeries per year	_
※Non- disclosure	Bone-related diseases	*	*	*	Showa University School of Medicine	*	*
of details	Ophthalmologic disease	*	*	*	Gifu Pharmaceutical University	*	* 11

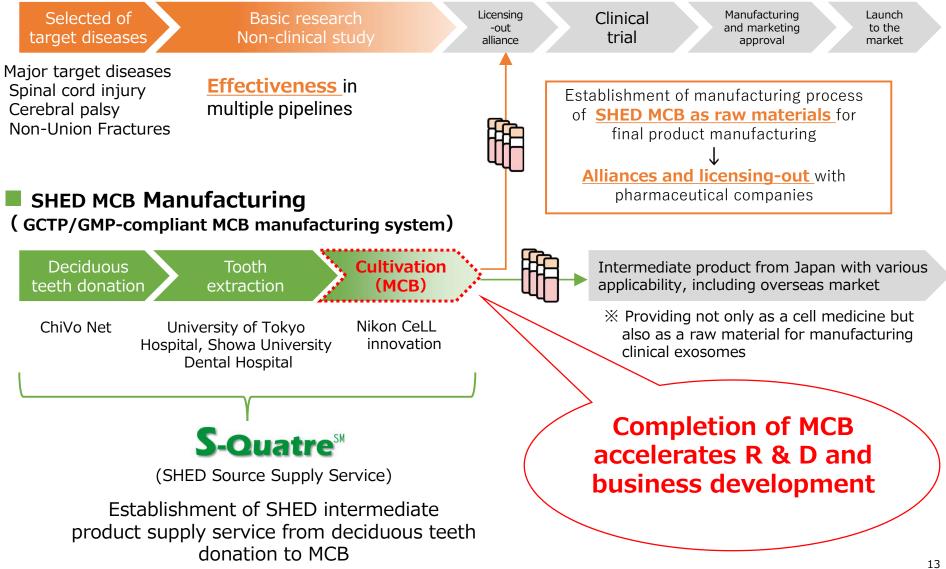
2<sup>nd</sup> Generation Cell Therapy : Designer Cell can Change Patients' Future



\* Created by Kidswell Bio Corporation referring from Strategic Proposal of Designer Cell by Japan Science and Technology Agency.



## **SHED:** Research & Development

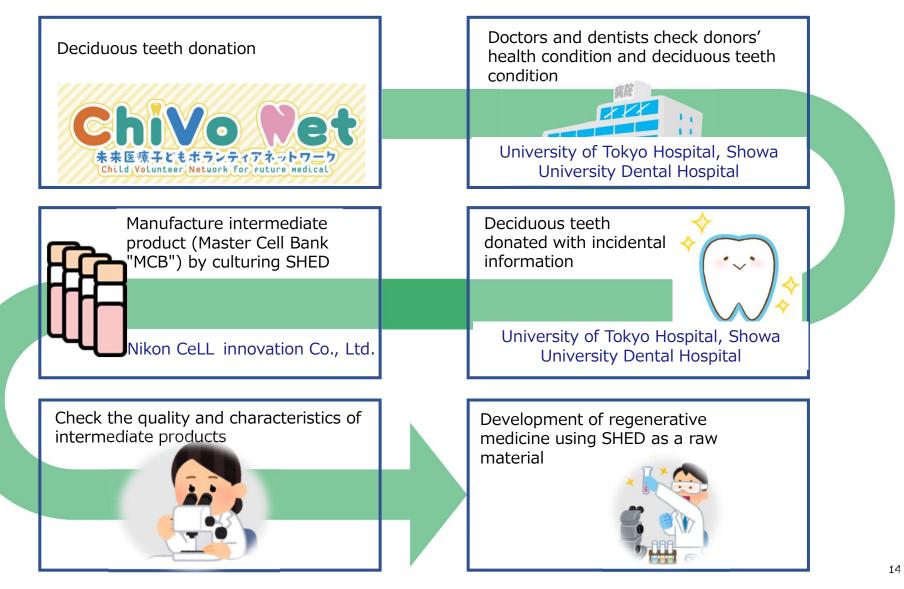


## **S-Ouatre**<sup>SM</sup> Tooth to Life-Changing Medicines

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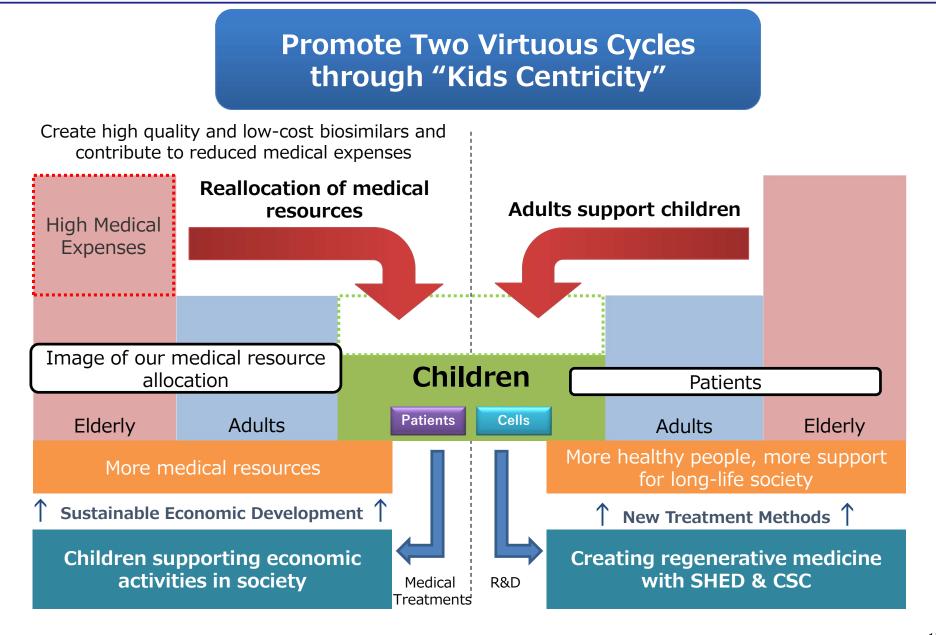
## **Service Service**

SHED intermediate product supply service



#### **Our Role in Society**

## **Kidswell**.Bio

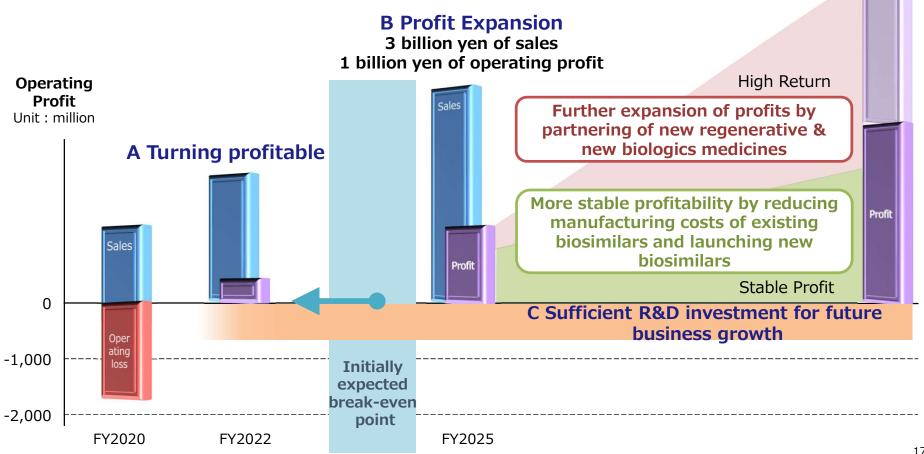


## Toward profitability in the fiscal year ending March 2023

#### The key to further growth is

#### to expand partnering for regenerative medicine and new biologics pipeline

- A) Turning profitable in FY2022
- B) 3 billion yen of sales and 1 billion yen of operating profit in FY2025 and huge profit expansion after 2025
- C) Sufficient R&D investment for future business growth



# Financial Forecast for FY2021-Consolidated (Year-on-year comparison)



Unit : thousands yen

Subject	Results for FY2020	Forecast for FY2021	Key points	
Gross sales	996,543	1,900,000	<ul> <li>Sales of drug substance of BS products and revenue related to royalties are steadily expanding.</li> <li>Expecting sales of new BS product, etc.</li> <li>Temporary fluctuation factors         <ul> <li>Drug substance sales related to the manufacturing process for the 4<sup>th</sup> biosimilar product</li> <li>Revenue from the completion of the MCB</li> </ul> </li> </ul>	
Cost of goods sold	119,571	1,020,000	<ul> <li>Maintaining high profit ratio of revenues related to sales of drug substance of BS products</li> <li>Regarding sales of the 4th BS product and MCB , the same amount is recorded as cost in order to collect the manufacturing cost as income for accounting purposes.</li> </ul>	
Gross profit	876,971	880,000	<ul> <li>Apparently, the gross profit ratio will drop due to temporary fluctuation factors except for the revenue from BS products.</li> </ul>	
Selling, general and administrative expenses	1,846,659	2,600,000		
Other expenses	882,791	800,000	<ul> <li>Continuously streamlining Selling, General and Administrative expenses</li> </ul>	
R&D expenses	963,868	1,800,000	<ul> <li>Investment in final development costs for commercial production of GBS-007</li> <li>Development costs for clinical trials and final product manufacturing of JRM-001</li> <li>Full-scale start of cost reduction measures for GBS-007 from this fiscal year and investing related cost</li> <li>Carrying over of R&amp;D expenses into FY2021</li> </ul>	
Operating	-969,687	-1,720,000	8	

# Strategy for achieving FY2022 Target (turning profitable)

### **Kidswell**.Bio

#### Financial Results in FY2020 and Forecast for FY2021

Unit : thousands yen

Results for		Forecast for FY2021			Strategy for achieving	
Subject	FY2020	Forecast	Basic figures for business forecast in the next fiscal year		FY2022 target	
Gross sales	996,543		1,350,000 w biosimilar expected.	Excluding temporary sales related to development of manufacturing process of 4 <sup>th</sup> biosimilar products and establishment of MCB	Increasing sales based on three BS products and income from development	
Cost of goods sold	119,571	1,020,000	350,000	Excluding temporary sales related to development of manufacturing process of 4 <sup>th</sup> biosimilar products and establishment of MCB	milestone(+licensing- out)	
Gross profit	876,971	880,000	1,000,000	Achieving the first billion yen	Achieving 1 billion yen+a	
Selling, general and administrative expenses	1,846,659	2,600,000	1,520,000	BS only	Maintaining 800 million yen	
SG&A expenses excl. R&D expenses	882,791	800,000	800,000		Accelerating R&D efficiency with around 700 million yen to promote licensing-out	
R&D expense	963,868	1,800,000	720,000	Final development costs for GBS- 007 before the launch and R&D expense related to JRM-001 <sup>*</sup> are excluded		
Operating profit	△969,687	△1,720,000	$\triangle$ 520,000	profit and loss statement varies depending	Turning profitable	

# Putting our FY2022 "turn profitable" strategy into numbers

### Kidswell.Bio

	FY 2021 Analytical value	Increase / decrease factor	FY2022 Planning goal
Gross sales	1.35 billion yen	Adding Full-year sales of GBS-007	<b>1.35 billion yen or more</b> Steady increase in sales of BS products and development milestones, etc. + Further upside with income from licensing-out
Gross profit	1 billion yen Gross profit from BS only	Same as above	1 billion yen <mark>or more</mark>
R&D expense	700 million yen	<ul> <li>✓ Further reduction of manufacturing costs</li> <li>✓ Efficient R &amp; D investment to increase licensing-out probability</li> </ul>	<ul> <li>500 to 800 million yen</li> <li>Peaking out manufacturing and development costs of GBS-007</li> <li>Reducing the development costs of JRM-001 due to alliance</li> <li>R&amp;D investment of 500 million yen is essential to achieve the target of our mid-term strategic plan</li> </ul>
SG&A expenses excl. R&D expenses	800 million yen	Maintain the status quo	<ul> <li>700 to 800 million yen</li> <li>Continuously streamlining Selling, General and Administrative expenses</li> <li>The actual fixed cost that is not I inked to sales is 650 million yen.</li> </ul>

#### The lowest gross profit line for profitability is 1.2 billion yen

- "200 million yen" additional gross profit is enough based on the FY2021 analytical value

- $\rightarrow$  To be achieved by full year sales of GBS-007 (only partial in FY2021) and development milestones, etc.
- R&D expenses for future growth can be increased while looking at maximizing profitability depending on licensing-out-related income (More income, more spending accordingly)

## Summary

## Kidswell.Bio

#### Progress of SHED regenerative medicine business contributes to the enhancement of KWB's corporate value

- Establishment of S-Quatre
- Started GMP production of Master Cell Bank (MCB)
- Progress of non-clinical studies in multiple SHED pipelines (Positive effectiveness is shown.)
- Development of a designer cell as reinforced cell therapy utilizing SHED

#### Positive path to profitability

- Launching GBS-007 (biosimilar of ranibizumab) to the market and partially contributed to our sales this fiscal year
- Development of our fourth biosimilar product
- With our unique business Model, even with R & D investment of 500 million yen, future growth can be fully realized.



# KIDS WELL, ALL WELL

# **Kidswell Bio Corporation**