

Financial Results for 2Q FY 2022

(Fiscal Year Ending March 31, 2023)

November 8, 2022

Kidswell Bio Corporation



Business and Financial Highlights in 2Q FY 2022

Financial Highlights in 2Q FY 2022

- ✓ Expanding the biosimilar sales led by sales growth of GBS-007.
- ✓ Recorded the sales related to completion of GMP-compliant SHED MCB.
- ✓ Recorded operating profit due to solid gross profit growth and reduced investment in SHED projects until confirming the MCB completion.

Business Highlights in 2Q FY 2022

Cell Therapy (Regenerative Medicine)

- Transferred all shares of JRM (Japan Regenerative Medicine Co., Ltd.) to Metcela Inc. (Development of JRM-001 is led by Metcela, Inc.).
- Completed GMP-compliant SHED MCB.
- Executed a master service agreement with Showa Denko Materials Co., Ltd. for the development of manufacturing process for the regenerative medicine products utilizing SHED and manufacturing investigational new drugs.
- Filed patent application on cell therapy for cerebral palsy utilizing SHED with Tokai National Higher Education and Research System.
- Published the research articles in collaboration with Hamamatsu University School of Medicine (Proof of concept of the potential therapeutic application of next generation SHED for brain cancer).

New Biologics

- Executed a research collaboration agreement with Chiome Bioscience Inc. (Chiome) on the development of antibody drugs.

Biosimilars

- Recorded strong sales due to more orders of GBS-007 than expected.

Others

- Sifted to non-consolidated financial result from 1Q FY 2022 due to transfer of the subsidiary (Japan Regenerative Medicine Co., Ltd.).
- Completed financing for working capital and facility reinforcement due to increased order of GBS-007.

Financial Results in 2Q FY 2022 (PL): Income Statement

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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Gross profit expansion due to biosimilar business
Selling, general and administrative e xpenses	915,868	684,018	2,180,000	
R&D expenses	532,689	251,787	1,400,000	<ul style="list-style-type: none"> Reduced investment in SHED business until confirming the completion of GMP-compliant SHED MCB
Other expenses	383,178	432,230	780,000	<ul style="list-style-type: none"> Continuously streamlining expenses and recorded expenses as scheduled
Operating profit	-450,932	11,137	-980,000	<ul style="list-style-type: none"> 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	

- Operating profit in the first half year of FY 2022 due to strong sales and reduced investment in SHED projects.
- Improved the probability of achieving 3 billion yen of sales and 1 billion yen of operating profit in FY 2025 due to expansion of biosimilar business.
- Positive investment in SHED projects from the latter half of FY 2022 for aiming at further sales and profit growth by licensing-out etc.

Financial Results in 2Q FY 2022: Balance Sheet

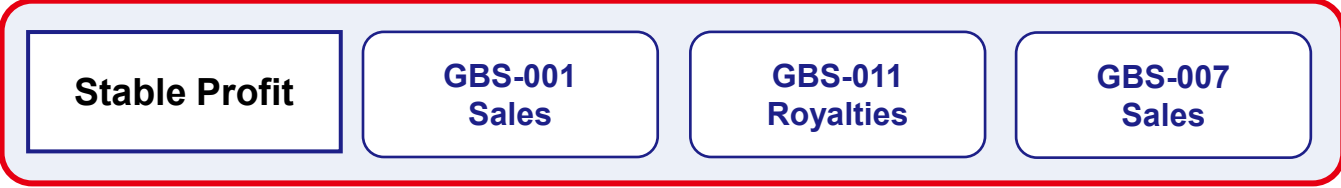
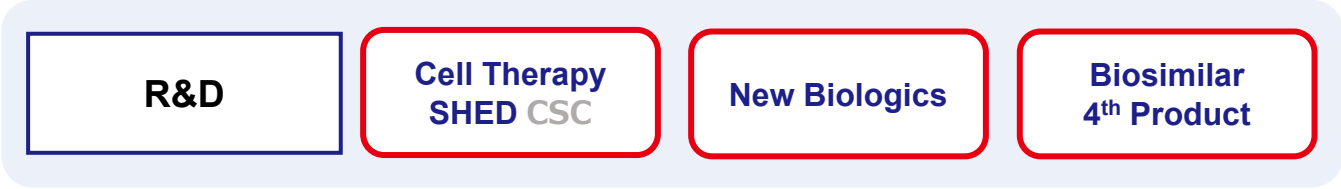
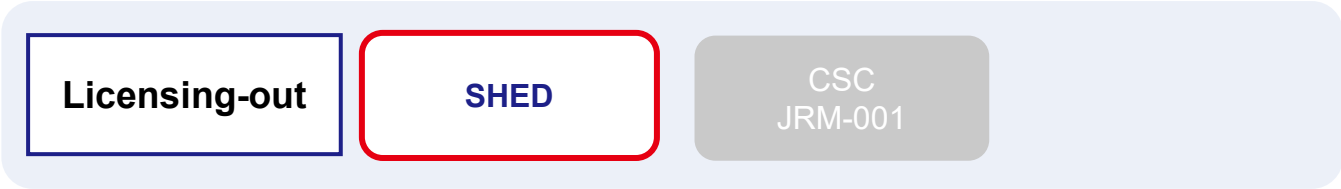
Unit : thousands yen

Subject	4Q FY2021 Consolidated	2Q FY 2022 Non-Consolidated	Highlights
Current assets	3,294,940	4,035,227	
(Cash and cash equivalents)	1,160,934	1,874,518	✓ Cash increased due to long-term loan from Mizuho Bank and the issuance of convertible bonds (CBs).
(Trade receivables)	461,854	650,697	✓ Due to positive sales growth of GBS-007
(Products)	200,118	213,888	
(In-process inventory)	788,696	504,388	
(Advance payments)	495,544	755,290	
(Long-term debts to be repaid within one year from a subsidiary)	600,000	—	
(Other current assets)	161,537	36,444	
(Allowance for doubtful accounts)	-573,745	—	
Non-current assets	175,396	224,719	
Total assets	3,470,336	4,259,946	
Current liabilities	1,111,168	651,641	
Non-current liabilities	656,260	1,908,555	✓ Due to long-term loan from Mizuho Bank and the issuance of CBs.
Total liabilities	1,767,428	2,560,196	
Total shareholders' equity	1,702,908	1,699,749	
Total liabilities and shareholders' equity	3,470,336	4,259,946	

- Improved cash balance while net assets ratio became lower due to long-term loan from Mizuho Bank and issuance of CBs.
- Accelerates investment in SHED projects due to increased cash balance and operating cashflow from biosimilar business.

Key Updates in Mid-Term Strategic Plan

 Progressing as scheduled



UPDATE !
Completion of SHED MCB

Key infrastructure for commercialization of cell therapy/ regenerative medicine products

UPDATE !
2nd generation SHED

Publication of the research articles in collaboration with Hamamatsu University School of Medicine

Strengthen profit structure led by GBS-007

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

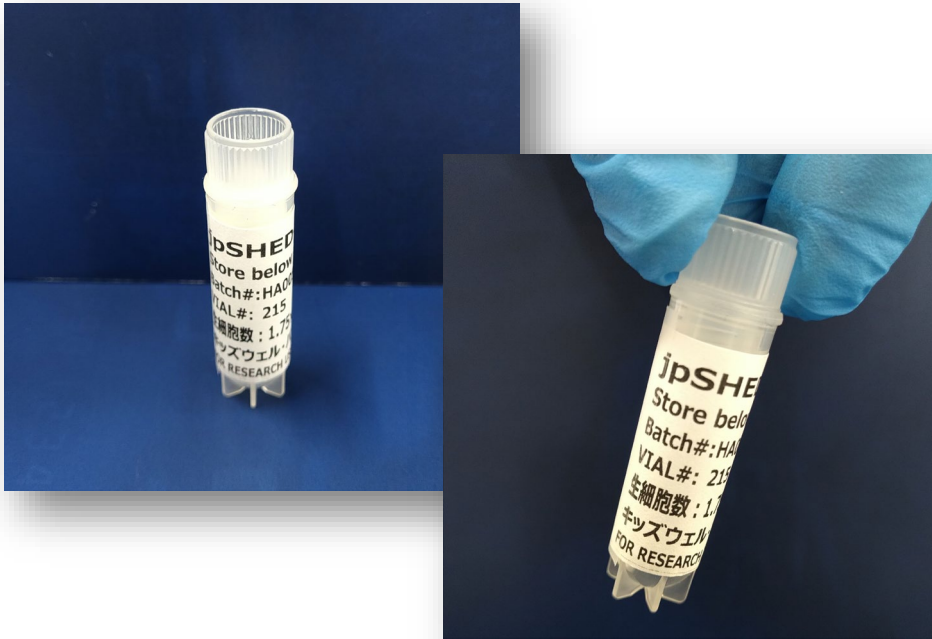
Biosimilar Business

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. Chione Bioscience Inc. MabGenesi

Key updates in cell therapy (SHED) business



Frozen SHED MCB in a storage tube*



SHED

Microscope image of SHEDs*

*Sample

Stable manufacturing & supply system of SHED MCB

From teeth donation to SHED MCB

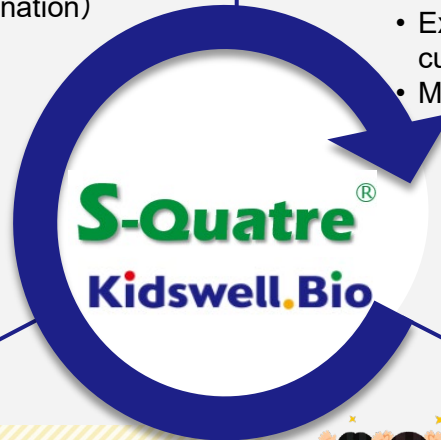
**Check donors' health condition
Extract deciduous teeth**

**University of Tokyo Hospital
Showa University Dental Hospital**

- Declaration of Consent
- Donor information management
- Donor screening (medical examination)
- Store and supply extracted teeth, etc.



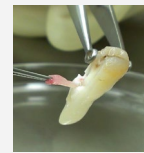
Deciduous teeth



Manufacture SHED Master Cell Bank in compliance with GMP

**Nikon CeLL innovation
(Cell and gene therapy process development and cell and gene therapy manufacturing service)**

- Receive extracted teeth
- Extract SHED from pulp tissue and culture
- Manufacture SHED Master Cell Bank



Master Cell Bank



Secure sufficient teeth donor candidates

Cell therapy products Development

Demand of raw materials

For launching the world's first SHED cell & gene therapy

SHED: 1st generation

Strive to establish SHED business

Target diseases: Diseases related to nervous, muscular and bone system

**Market potential:
Expect to grow 700 to 800 billion yen market size by 2040^{※1}
(Global)**

SHED: 2nd generation

Designer cells

Target diseases: Genetic disease, neurodegenerative disease and cancer

**Market potential:
Expect to grow over 1 trillion yen market size by 2028^{※2}
(e.g. CAR-T cell therapy: over 13.5 billion dollars in the world)**

SHED Supply Business

For other modalities

- **Products utilizing SHED-derived cell organs and extracellular vesicles (exosome and mitochondria, etc.)**
- **Drug Delivery System utilizing SHED**

**Market potential:
Expect hundreds of billions yen market size^{※3}**

SHED MCB



※1: KWB's research
※2 & 3: Estimated by KWB based on public information from various related institutions and organizations

Clinical manufacturing and high-quality investigational new drugs



3D bioreactors

Manufacturing cost reduction and quality improvement applicable to both adherent and suspension cells



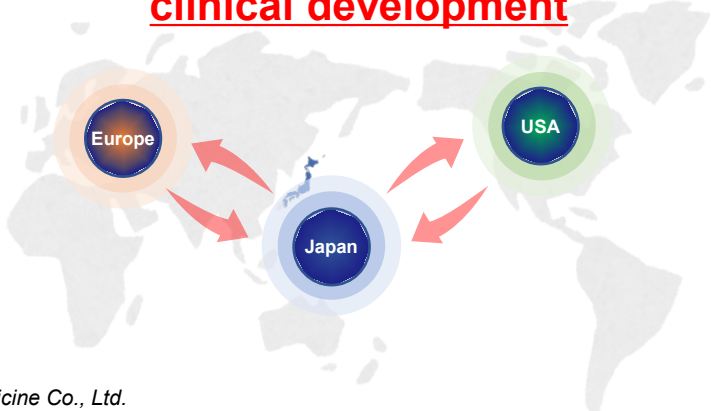
Stable culture expansion



Stable Supply of investigational new drugs



Accelerating global & domestic clinical development



※Permission for use of corporate logs and photos from Showa Denko K.K. and Minaris Regenerative Medicine Co., Ltd.

Commercialization: 1st generation SHED

Launching regenerative medicine products

- Establishment of SHED Supply system
 - **Completed GMP-compliant MCB and drive development of manufacturing method of investigational new drugs and implementation of the manufacturing**
- Selection of target diseases through collaborative researches
 - **Cerebral palsy and Spinal cord injury, etc.**
- Establishment of clinical development system
 - **Reinforcing organizational structure and procedures such as SOPs**



Nagoya Univ.

Hamamatsu Univ. School of Medicine

Technology

Invention in SHED and next generation technology

For commercialization of the 2nd generation SHED

- Introduction of next-generation technologies to generate synergies
 - **Potential therapeutic application of next generation SHED such as engineered SHED for brain cancer**
 - **Combination with synergistic devices**
- Promoting technology adoption through alliances and acquisitions
 - **Actively approaching potential partners for maximizing SHED value**

Fund-raising

Financing for strategic execution

- Financing from overseas market
- Large-scale financing to realize SHED commercialization
- Equity financing specialized for SHED development
 - **Approaching overseas funds/ VCs with acquired data and progress of research and development**

Human resources and organizational structure

Strengthening SHED development structure

- Establishment of a SHED delivery system to overseas
- Establishing office in overseas
 - ✓ Fostering networks with international medical institutions and academies
 - ✓ Strengthening cooperation between Japan and overseas
- Staff recruiting for global expansion
 - **Driving establishment of manufacturing system in complaint with FDA and EMA**
 - **Actively recruiting people for implementing and realizing growth strategies**

**Progress is shown in red.*

Development Product	Target disease	Symptom	Existing Treatment	Therapeutic target	Partners	Number of patients (Domestic) ※2	Number of patients (Global) ※2
1 st generation SHED	Pediatric disease Cerebral palsy	Quadriplegia and Posture disorder	None	Nerve protection, activation and regeneration	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
	Pediatric disease Congenital Isolated Hypoganglionosis	Intestinal obstruction	Enterectomy, colostomy	Ganglion regeneration	Mochida Pharmaceutical	100 patients	—
	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	—
	Ophthalmologic disease	※1	※1	※1	Gifu Pharmaceutical University	※1	※1
	Peripheral nerve palsy	Motor function and sensation disorder	Nerve reconstruction (Autologous nerve transplantation)	Peripheral nerve regeneration	Oita University	8,000 surgeries per year	—
	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
2 nd generation SHED	Brain cancer	Poor life prognosis	Surgery, radiation therapy, chemotherapy	Anticancer, prevention of recurrence	Hamamatsu University School of Medicine	20,000 patients per year	830,000 patients in total
	※1	※1	※1	※1	NanoCarrier, BioMimetics Sympathies	※1	※1

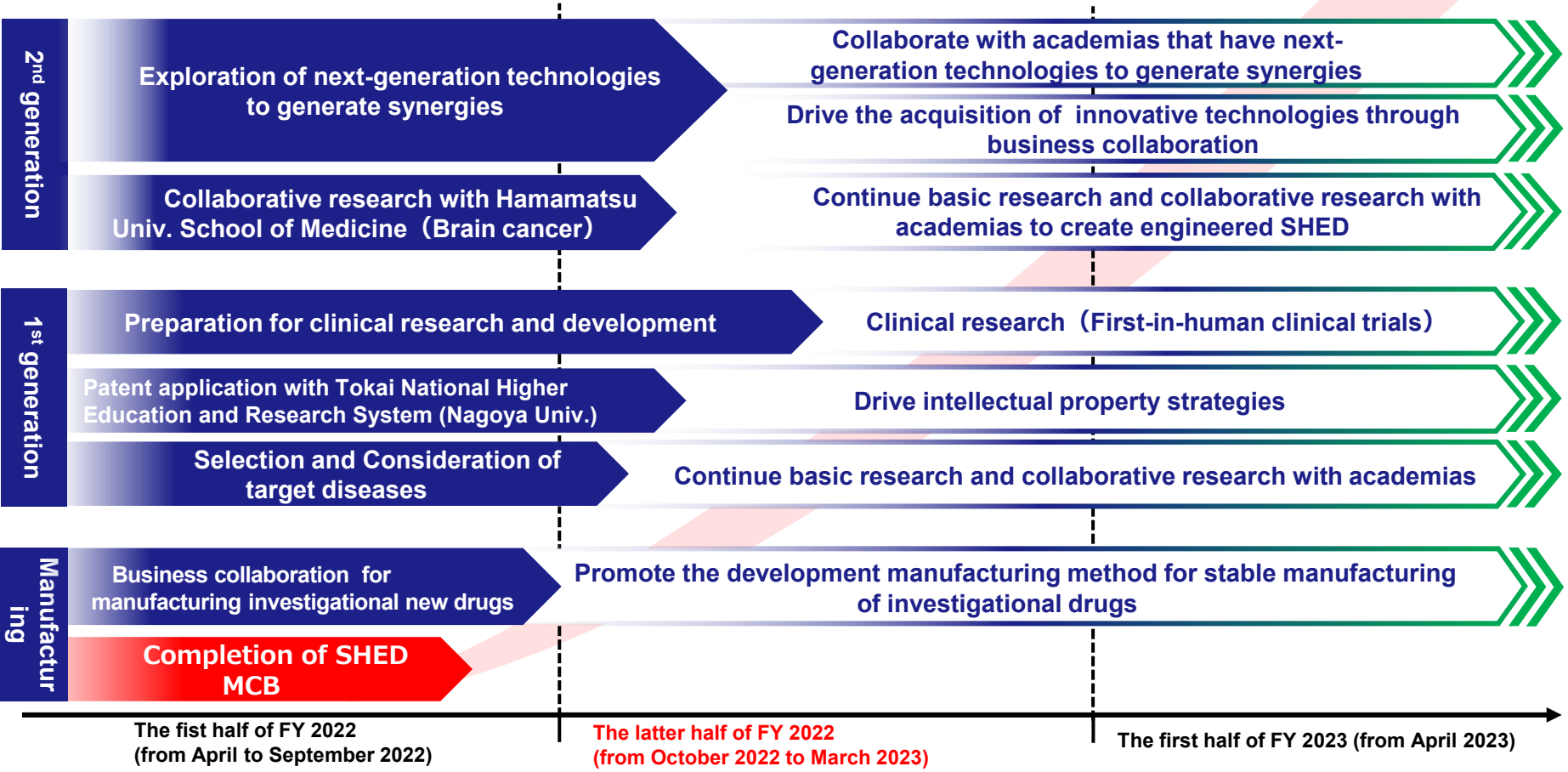
※1 Details not disclosed, ※2 KWB research based on public and relevant information

**For realization of the Mid-Term Strategic Plan –
KWB 2.0-**

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

Current progress

Future events with business progress

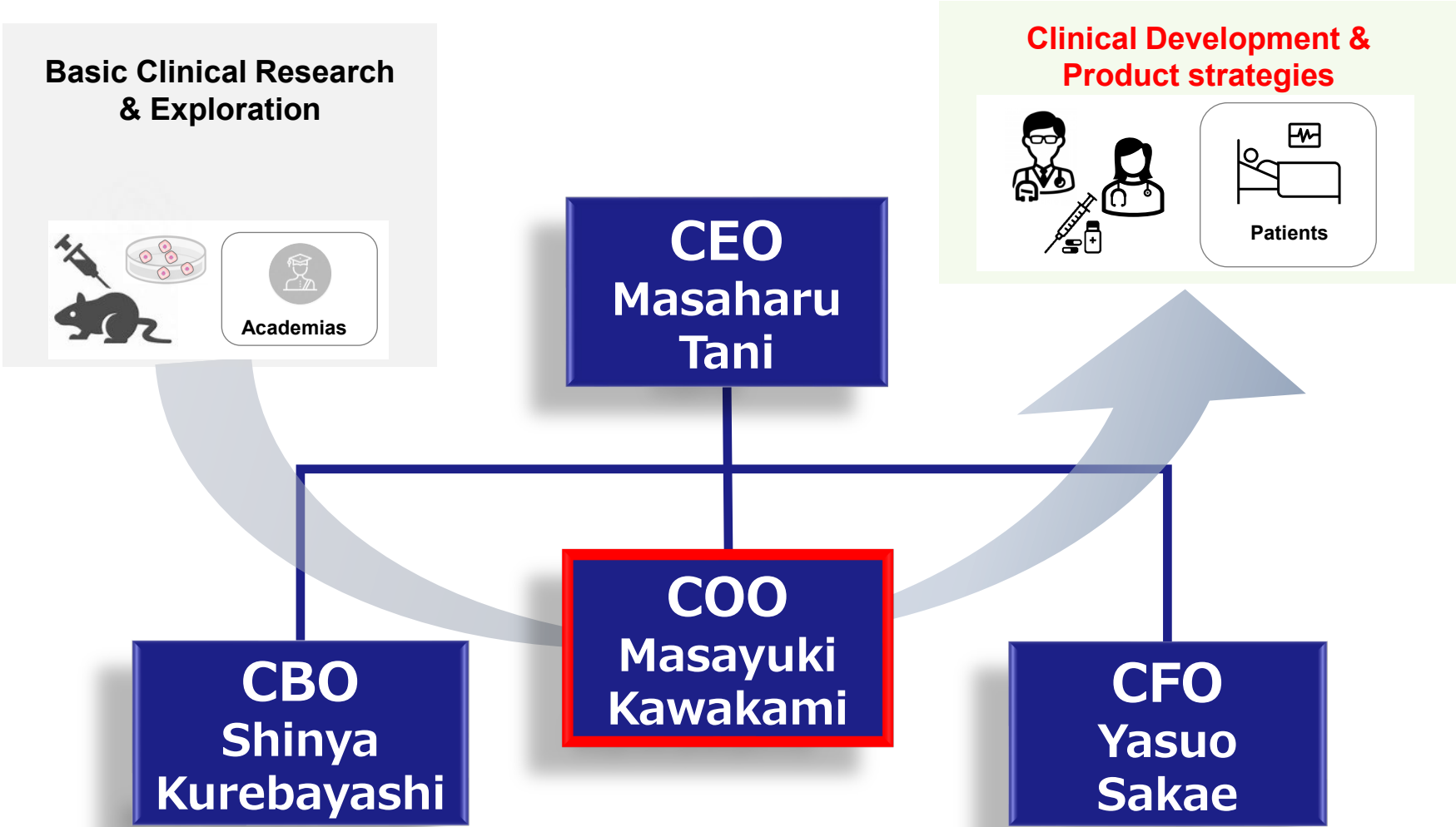


The first half of FY 2022 (from April to September 2022)

The latter half of FY 2022 (from October 2022 to March 2023)

The first half of FY 2023 (from April 2023)

Toward further growth and global expansion with the commercialization of SHED products



More focus on new products launch

COO's responsibilities (Chief Operating Officer)

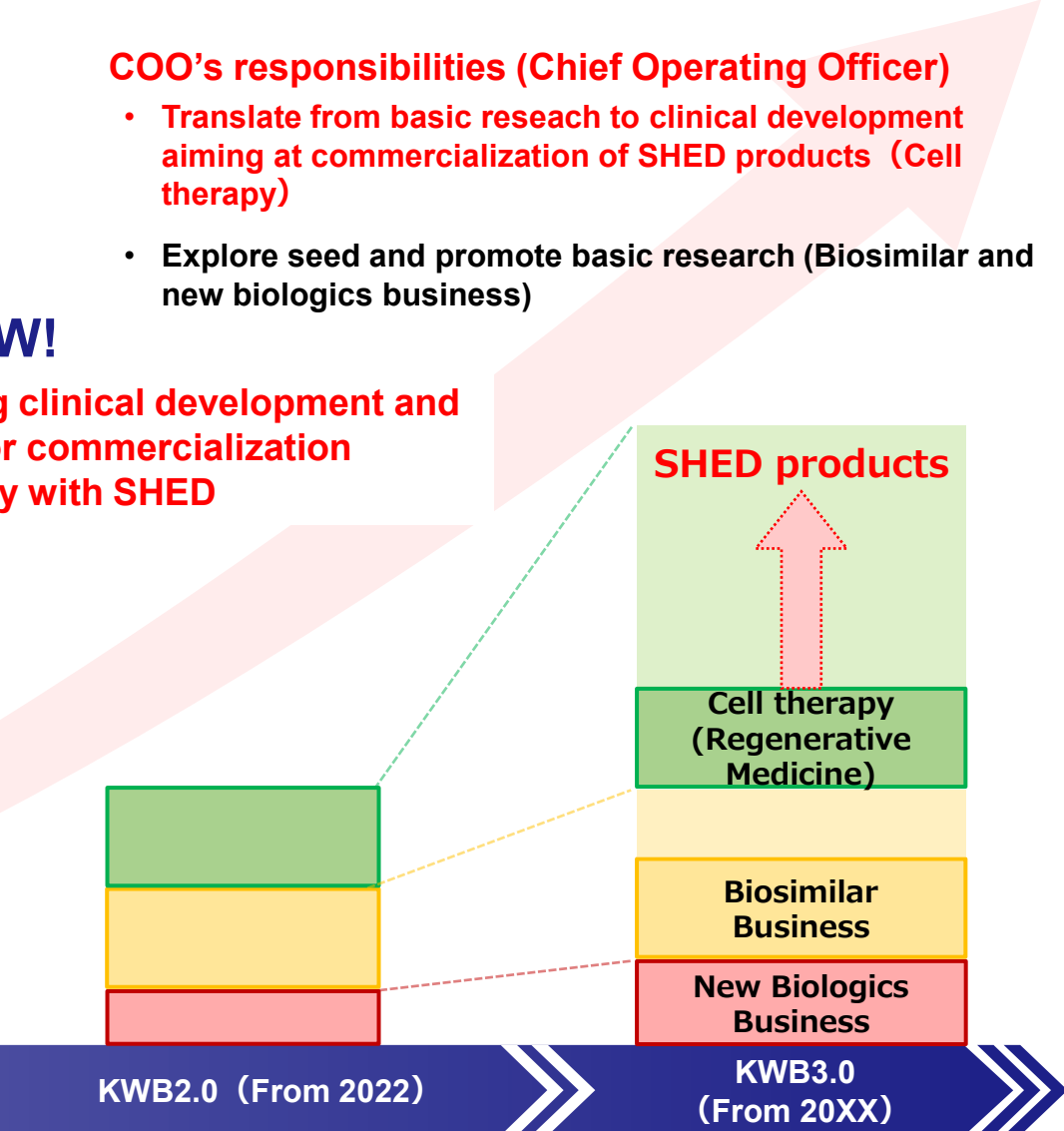
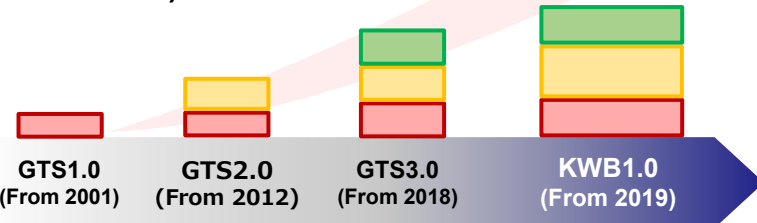
- Translate from basic research to clinical development aiming at commercialization of SHED products (Cell therapy)
- Explore seed and promote basic research (Biosimilar and new biologics business)

NOW!

Next stage for externalizing clinical development and product strategies for commercialization of cell therapy with SHED

CTO's responsibilities (Chief Technology Officer)

- Promoted development of manufacturing methods by combining existing technologies (Biosimilar business)
- Explored seeds exploration and promoting basic research (New biologics & cell therapy business)



KWB2.0 (From 2022)

KWB3.0 (From 20XX)

Accelerating our R&D activities to realize our vision

KIDS WELL, ALL WELL

SHED MCB:
Stable culture expansion
and supply

SHED MCB Competed

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 4th BS product
- New BS pipeline development

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

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

Founded (2001) to FY 2021
 FY 2022
 FY 2025 (Turning profitable)
 (3 billion yen of sales and 1 billion yen of operating profit)
 FY 2030 onward

All for Kids, Kids for All

KIDS WELL, ALL WELL



Term	Explanation
Cell therapy (Regenerative Medicine)	Cell therapy is the transplantation of human or animal cells to replace or repair damaged tissue. It includes utilizing immune cells in the blood, adipose-derived and born-derived mesenchymal stem cells.
Designer cells	Designer cells can enhance therapeutic efficacy and cell directionality for disease sites. They are of interest in the field of diseases without radical cure as a medical treatment of next generation.
Exosome	A tiny vesicle created and released from the plasma membrane of various types of cells, especially immune cells, and capable of inducing antigen-specific immune responses. Exosomes are of special interest in the field of medicine with their special ability.
EMA	European Medicines Agency The European Medicines Agency (EMA) is a decentralized agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
FDA	Food and Drug Administration The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also provides accurate, science-based health information to the public.
GMP	Good Manufacturing Practice (GMP) is minimum required guidelines that a manufacturer must meet to assure that their products are consistently high in quality and work for their intended use. GMP is a part of a quality system covering the manufacture and testing of pharmaceutical ingredients, foods, pharmaceutical products, diagnostics, and medical devices.

Term	Explanation
Master Cell Bank (MCB)	Master Cell Bank (MCB) is cells for medical treatments that are expanded under the constant culture condition and divided into several vials for long frozen storage. Frozen MCB can be expanded again after thawing and utilized for regenerative medicine products as a raw material.
SHED	SHED : S tem cells from H uman E xfoliated D eciduous teeth SHED is a mesenchymal stem cell (MSC) extracted from a dental pulp cavity inside exfoliated deciduous teeth and is easy to differentiate into bone and nerve cells. Especially SHEDs from young donors have shown higher proliferative activity and secretory capacity of various growth factors (particularly neurotrophic factors) compared to stem cells from other tissues.

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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 advices.