



Security Code:  
4584

# Financial Results for 2Q FY 2023

## (Fiscal Year Ending March 31, 2024)

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Nov. 8, 2023

### **Biotech Striving for Value Creation**

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

# **Kidswell Bio Corporation**

- ◆ **Financial Highlights in the 2Q FY2023**
  
- ◆ **Business Highlights**
  - Biosimilar Business**
  - Cell Therapy Business (Regenerative Medicine)**
  
- ◆ **Growth Strategies**
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# **Financial Highlights in 2Q FY2023**

# Financial Results in 2Q FY 2023 (PL): Income Statement

Unit : thousands yen

Subject	Results for 2Q FY2022	FY2023 ending March 31, 2024		Forecast	Progress rate
		Results for 2Q	Year-on-year ratio		
<b>Gross sales</b>	1,116,111	581,870	52%	3,500,000	17%
Cost of goods sold	420,954	351,901	84%		
<b>Gross profit</b>	695,156	229,968	33%		
Selling, general and administrative expenses	684,018	949,627	139%		
R&D expenses	251,787	546,693	217%	1,600,000	34%
Other expenses	432,230	402,933	93%		
<b>Operating loss</b>	11,137	-719,658	--	-1,500,000	--
Net loss	-42,082	-744,646	--	-1,550,000	--
<b>Net loss for the quarter</b>	-42,687	-780,251	--	-1,550,000	--

- Progressing as planned for the forecast of FY2023.
- Contributions to sales from BS products, including the strong sales of GBS-007, are expected after the second half of the year.
- Gross profit declined in this quarter due to the depreciation of the yen and overseas inflation, in addition to the elimination of the impact on sales of temporary income from the completion of master cell bank (MCB), which was recorded in the same quarter of the previous year.

# Financial Results in 2Q FY 2023: Balance Sheet

Unit : thousands yen

Subject	4Q FY2022	2Q FY2023
Current assets	3,697,155	3,031,859
(Cash and cash equivalents)	1,067,162	622,231
(Trade receivables)	1,088,766	578,193
(Products)	213,007	258,596
((In-process inventory)	422,308	671,905
(Advance payments)	821,536	816,463
(Other current assets)	84,373	84,468
Non-current assets	197,609	161,978
<b>Total assets</b>	<b>3,894,765</b>	<b>3,193,837</b>
Current liabilities	1,055,839	731,434
Non-current liabilities	1,605,420	1,387,290
Total liabilities	2,661,259	2,118,724
Total shareholders' equity	1,233,505	1,075,113
<b>Total liabilities and shareholders' equity</b>	<b>3,894,765</b>	<b>3,193,837</b>

- With the funds acquired through equity financing, (1) manufacturing in the biosimilar business proceeded as planned, and (2) cash and deposit balances and stock capital improved.
- The company expects to improve capital efficiency by shortening the recovery period for manufacturing costs through the cooperation and support of partner companies.

# **Business Highlights**

- ① **【Biosimilar Business】**
  - **Received Manufacturing and Sales Approval for GBS-010 (Pegfilgrastim biosimilar)**
  
- ② **【Cell Therapy Business (Regenerative Medicine)】**
  - **Enrolled the first case of clinical research for children with cerebral palsy under the initiative of Nagoya Univ.**
  - **Completed a part of PMDA consultation for entry into a corporate clinical trial for children with cerebral palsy.**

# Biosimilar Business

Received Manufacturing and Sales Approval for GBS-010  
(Pegfilgrastim biosimilar)



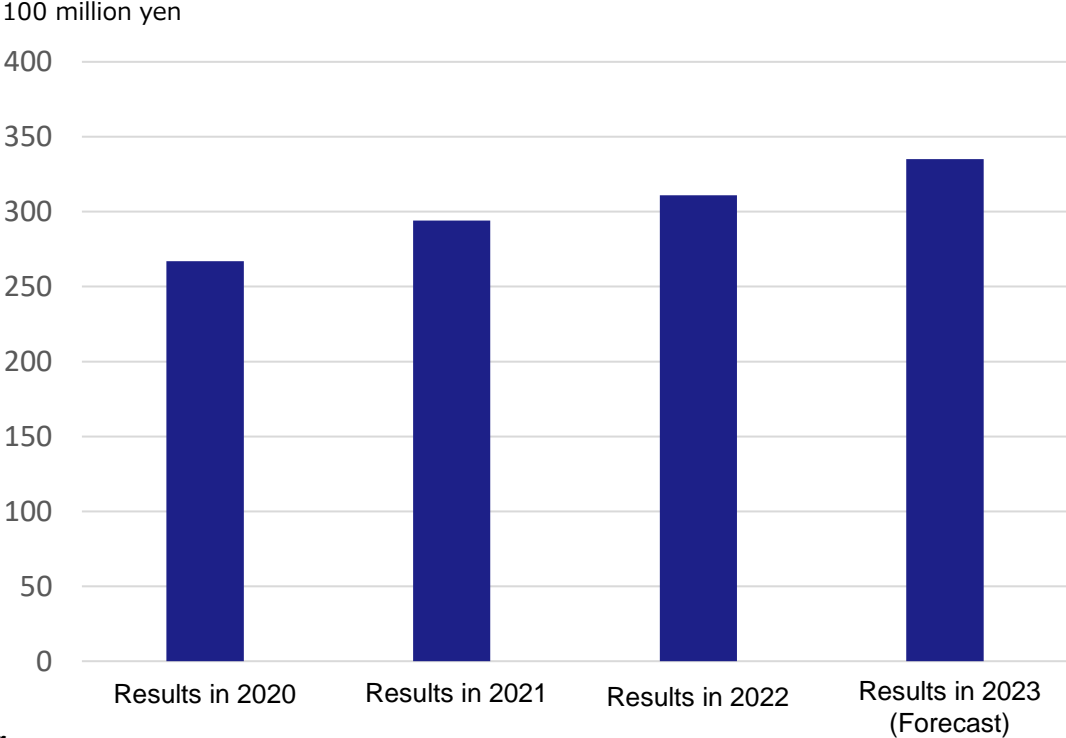
- Received manufacturing and sales approval for GBS-010 in Sept. 2023
- Launched the fourth BS product

**Outline of GBS-010**

<b>Development Partner</b>	<b>Mochida Pharmaceutical Co., Ltd.</b>
<b>Generic name</b>	<b>Pegfilgrastim biosimilar</b>
<b>Indication</b>	<b>Suppression of the onset of febrile neutropenia*1 by cancer chemotherapy</b>
<b>Competitors</b>	<ul style="list-style-type: none"> <li>• Biosimilar of sustained G-CSF preparation pegfilgrastim</li> <li>• <b>Approved as the first biosimilar for its originator, G-Lasta (Pegfilgrastim) (Sales starting by the end of 2023)</b></li> </ul>

\*1:Febrile neutropenia is a condition with fever in which neutrophils, which are responsible for eliminating pathogens that cause infection, decrease due to side effects of drugs for cancer.

Pegfilgrastim market (including originators and biosimilars) is expected to continue to expand on a volume basis.



<Sales trend in G-Lasta (Pegfilgrastim) \*2>

- While many domestic pharmaceutical companies are promoting small molecule drug business, KWB has been accumulating experience, know-how, and human resource development in biopharmaceuticals, on which global pharmaceutical companies focus.
- Four biosimilars clinically developed with partner companies have been launched.

**GBS-001**  
Filgrastim BS  
(Approved in Nov. 2012)  
Fuji Pharma Co., Ltd.



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

**GBS-011**  
Darbepoetin alfa BS  
(Approved in Sept. 2019)  
Sanwa Kagaku Kenkyusho Co., Ltd.



- Biosimilar of continuous Erythropoiesis Stimulating Factor Preparation Darbepoetin alfa

**GBS-007**  
Ranibizumab BS  
(Approved in Sept. 2021)  
Senju Pharmaceutical Co., Ltd.



- Biosimilar of anti-VEGF antibody drug ranibizumab
- Strong sales and more orders than expected
- Received an approval of partial modification of pharmaceutical manufacturing approval for macular edema associated with retinal vein occlusion as additional indication of Ranibizumab BS in Sept. 2023

**GBS-010**  
Pegfilgrastim BS  
(Approved in Sept. 2023)  
Mochida Pharmaceutical Co., Ltd.

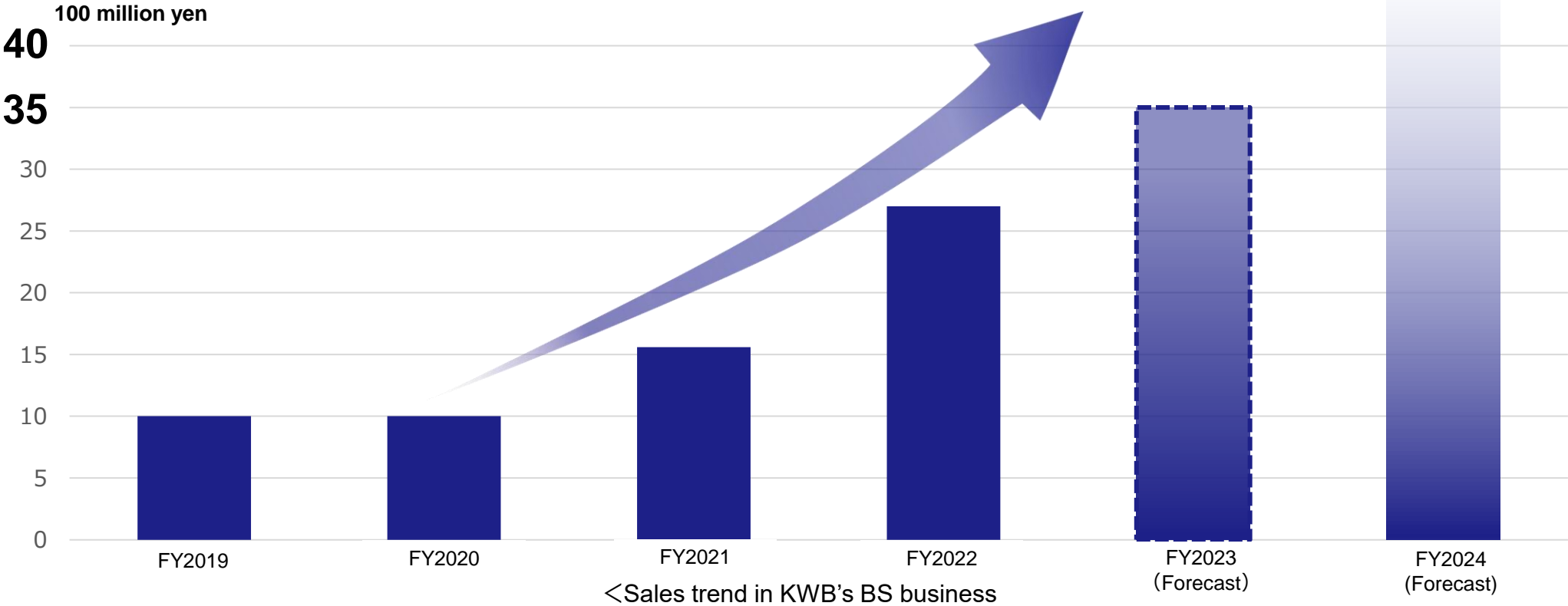


- Biosimilar of sustained G-CSF preparation pegfilgrastim
- No biosimilars have been approved by competitors as of Sept. 2023.

- Eighteen biosimilars approved in Japan
- Replacement rate (BS share) of GBS-001 and GBS-011 developed by KWB is more than 80% on a volume basis. (BS share includes other companies' biosimilars)
- GBS-007 and GBS-010 have not been approved as competitors at this time, and their market share is expected to increase.

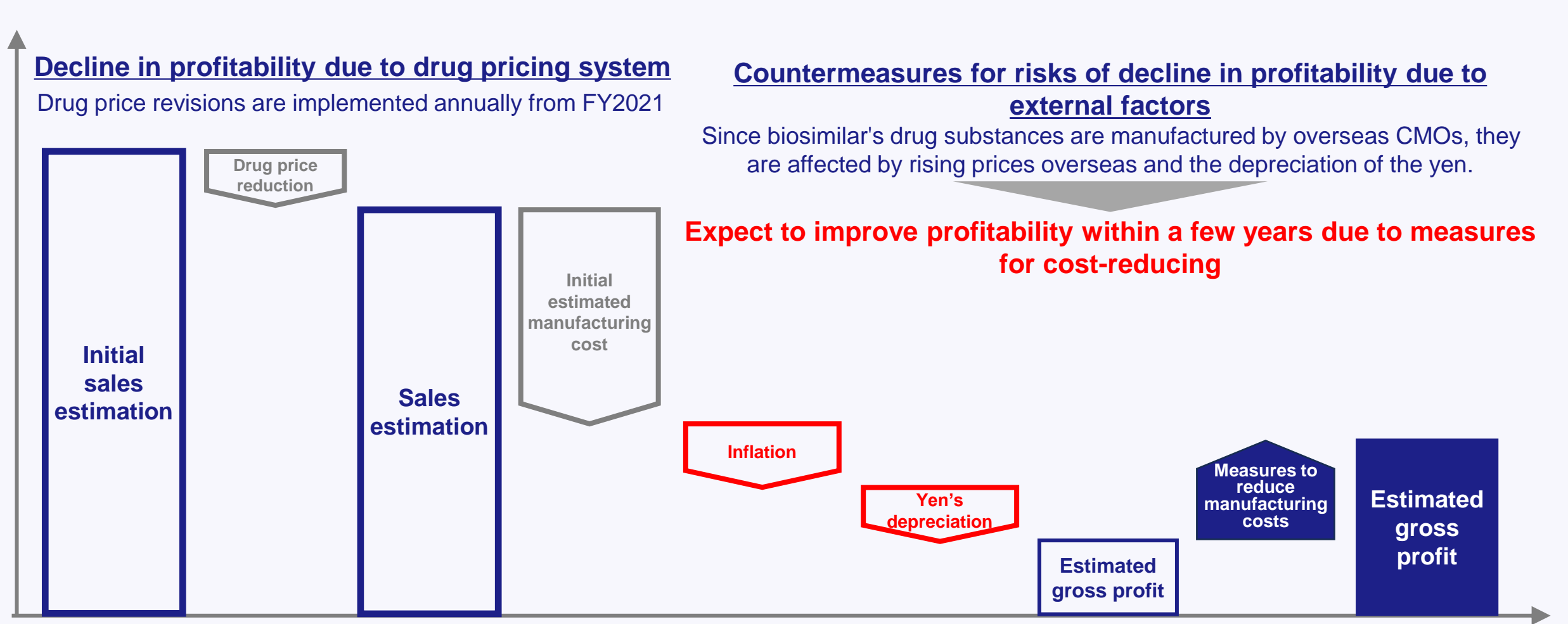
	Biosimilars (BS)	Originators	Approval
No competitors	1 Ustekinumab BS	Stelara Subcutaneous Injection	Sept. 2023
	2 <b>Pegfilgrastim BS (GBS-010)</b>	G-LASTA Subcutaneous Injection	<b>Sept. 2023</b>
No competitors	3 <b>Ranibizumab BS (GBS-007)</b>	LUCENTIS kit for intravitreal injection	<b>Sept. 2021</b>
	∴ ∴	∴	∴
Over 80% of BS share	7 Teriparatide BS	Forteo Subcutaneous injection	Sept. 2019
	8 <b>Darbepoetin alfa BS (GBS-011)</b>	NESP INJECTION PLASTIC SYRINGE	<b>Sept. 2019</b>
	∴ ∴	∴	∴
Over 80% of BS share	15 Infliximab BS	REMICADE for I.V.Infusion	July 2014
	16 <b>Filgrastim BS (GBS-001)</b>	GRAN INJECTION	<b>Nov. 2012</b>
	17 Epoetin Alfa BS	ESPO INJECTION	Jan. 2010
	18 Somatropin BS	Genotropin	Jun. 2009

- Launch of GBS-010 and approval of additional indications for GBS-007 are expected to lead to steady earnings growth in the biosimilars business.
- Based on medium-term demand forecasts from partner companies, KWB plans to manufacture and deliver BS products for stable supply.
- Drug substance and others, which are scheduled to be recorded in sales for the current fiscal year, may be recorded in the next fiscal year due to adjusting the timing of manufacturing and delivery.

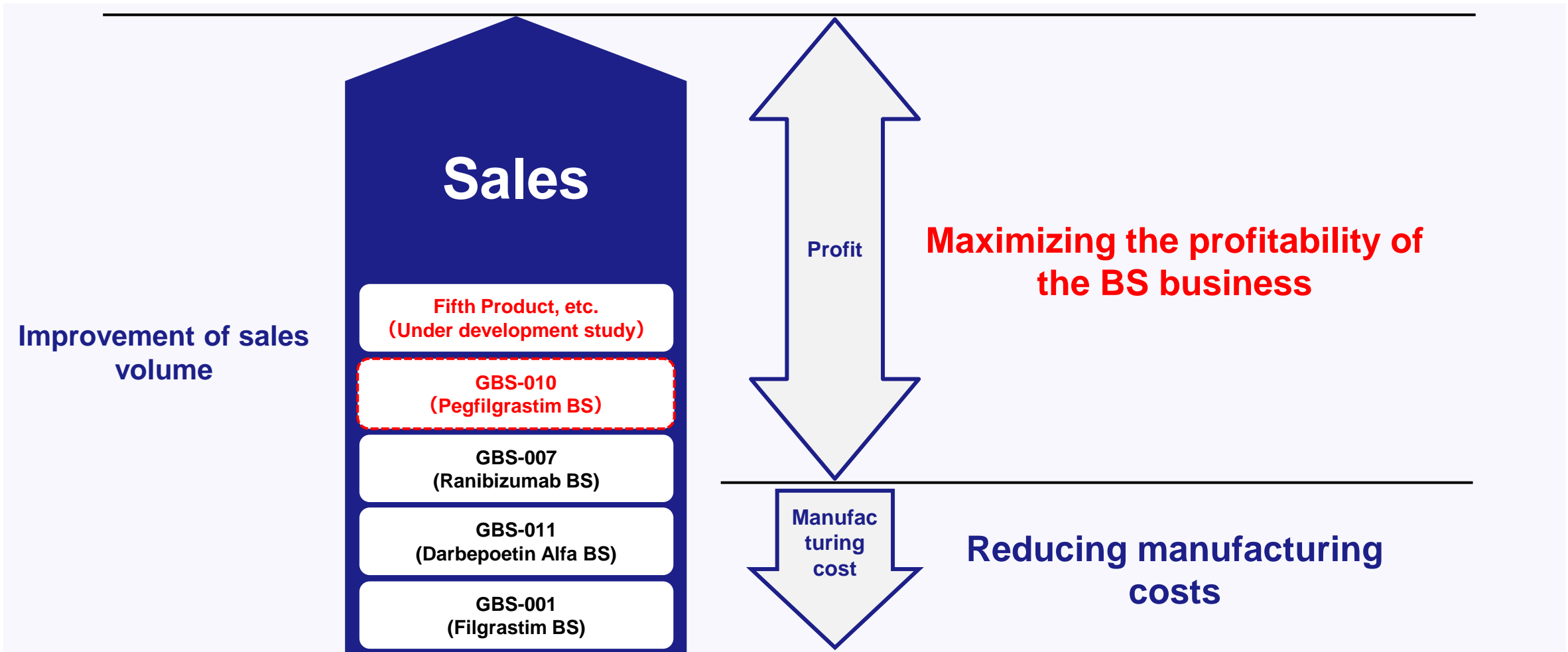


<Sales trend in KWB's BS business

Recognize the risk of a decline in profitability in the biosimilar business due to the external environment changes  
Promote to expand profitability by reducing cost and other measures



Maximize profits from biosimilars business and secure funds of growth investments by maximizing sales of BS launched, implementing measures to improve profitability, and launching new BS pipeline.



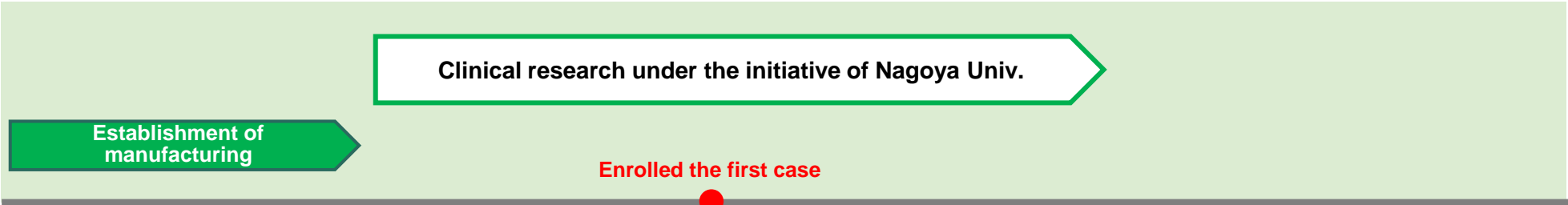
## **Cell Therapy Business (Regenerative Medicine)**

- **Enrolled the first case of clinical research for children with cerebral palsy under the initiative of Nagoya Univ.**
- **Completed a part of PMDA consultation for entry into a corporate clinical trial for children with cerebral palsy.**

Started enrolling the first case of clinical research under the initiative of Nagoya Univ.  
 Proceed preparation for corporate clinical trials under the initiative of KWB

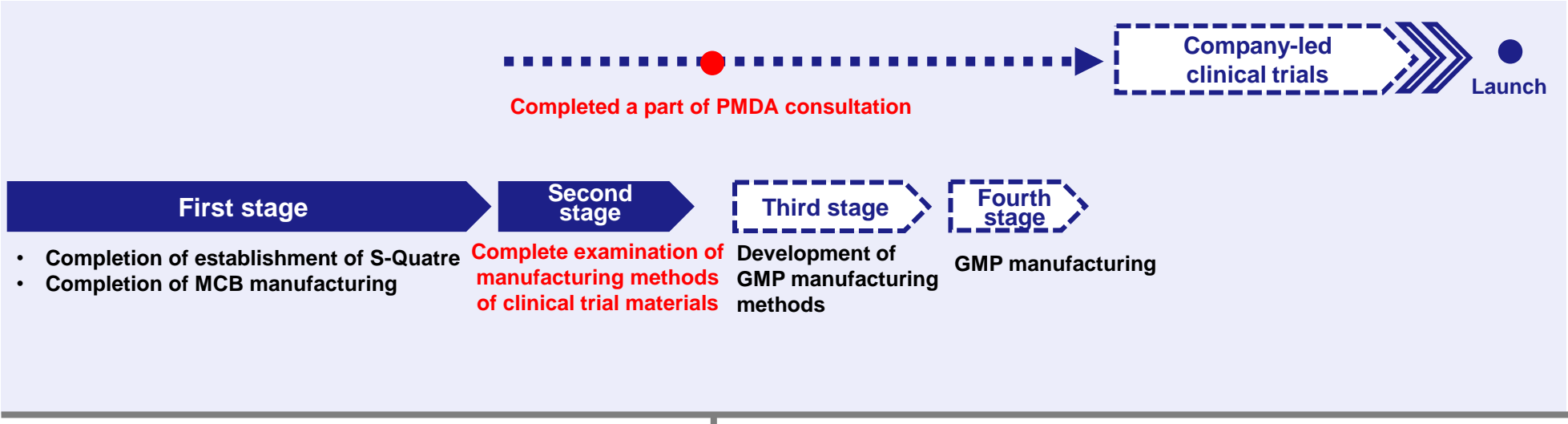
### Autologous cells

- Mainly confirm safety using the patient’s SHED
- Can be administered to the patient self



### Allogenic cells

- Confirm the effectiveness and safety using SHED (allogenic SHED) from healthy donors
- Can be administrated to many patients

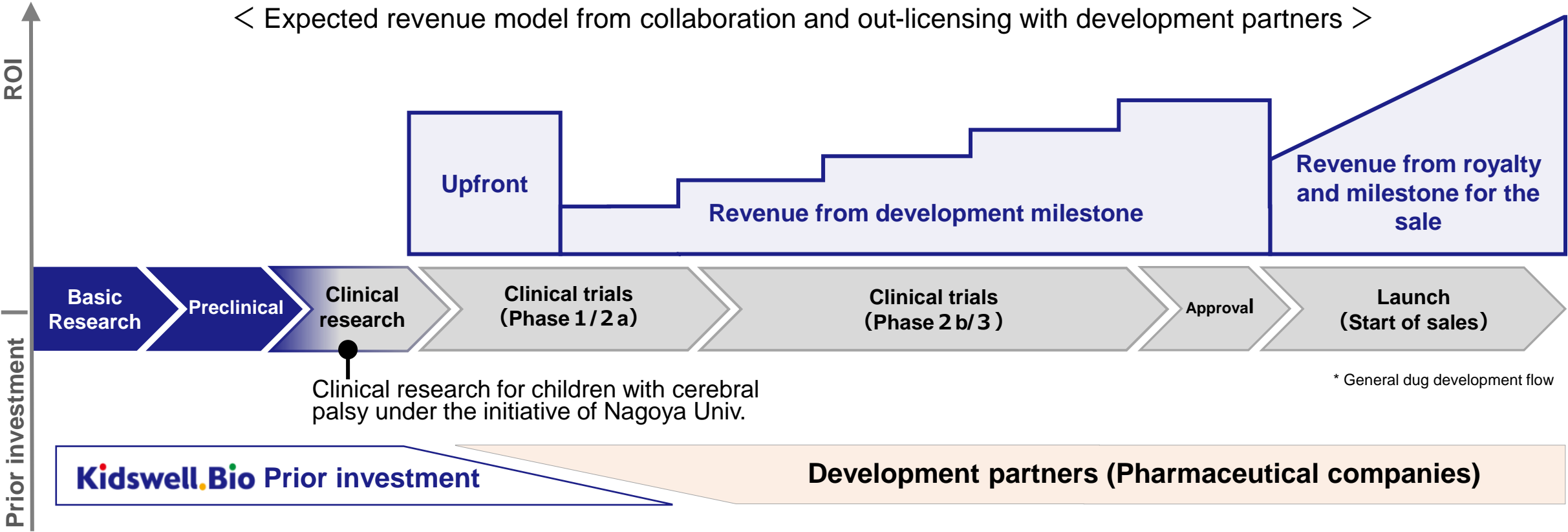


FY2023 (Present)



With the progress of the clinical development of SHED, active discussions with development partners for conducting agreements has been started.

Expect to secure revenue from the cell therapy business following the conclusion of the agreements.



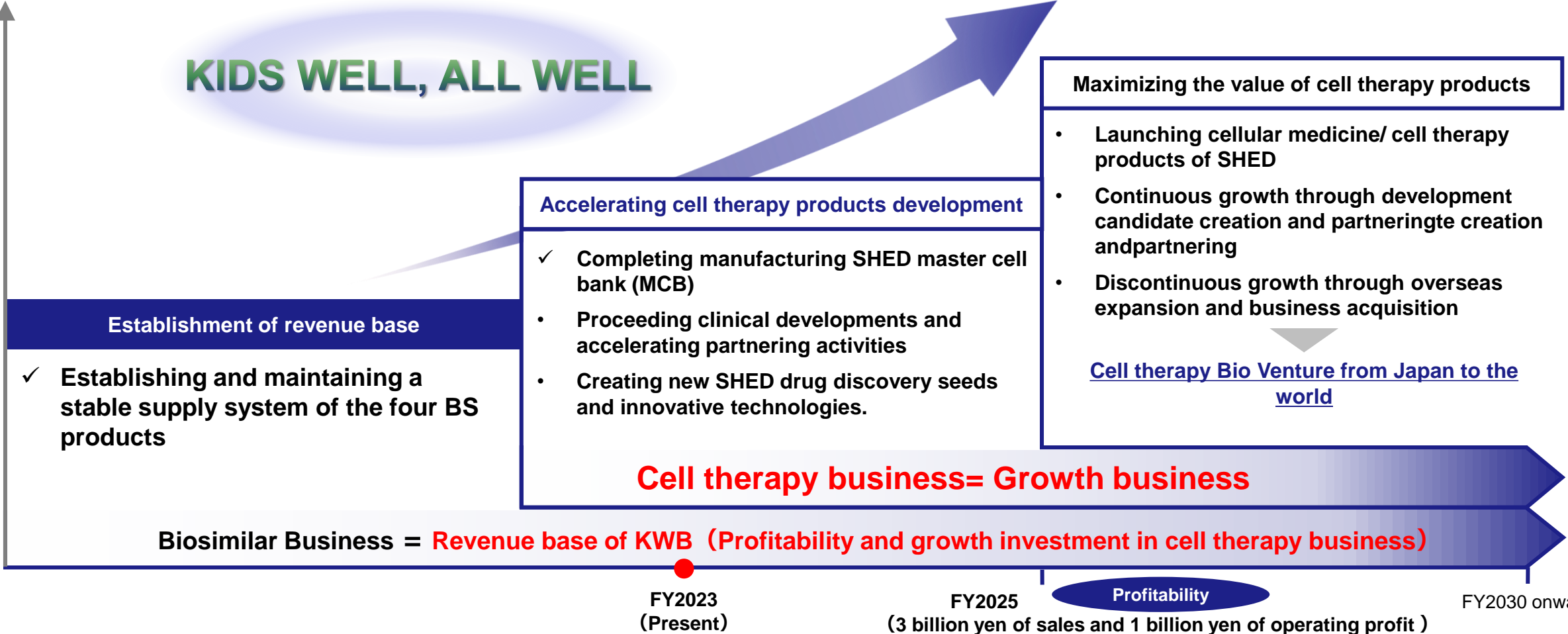
# **Growth Strategies**

To increase shareholders' value, KWB will strengthen "visualize the improvement of business value".

- The goal of establishing a revenue base from the biosimilar business is in sight.
- KWB will implement clinical development of SHED and proceed partnering activities according to SHED pipeline progress.

Corporate Value

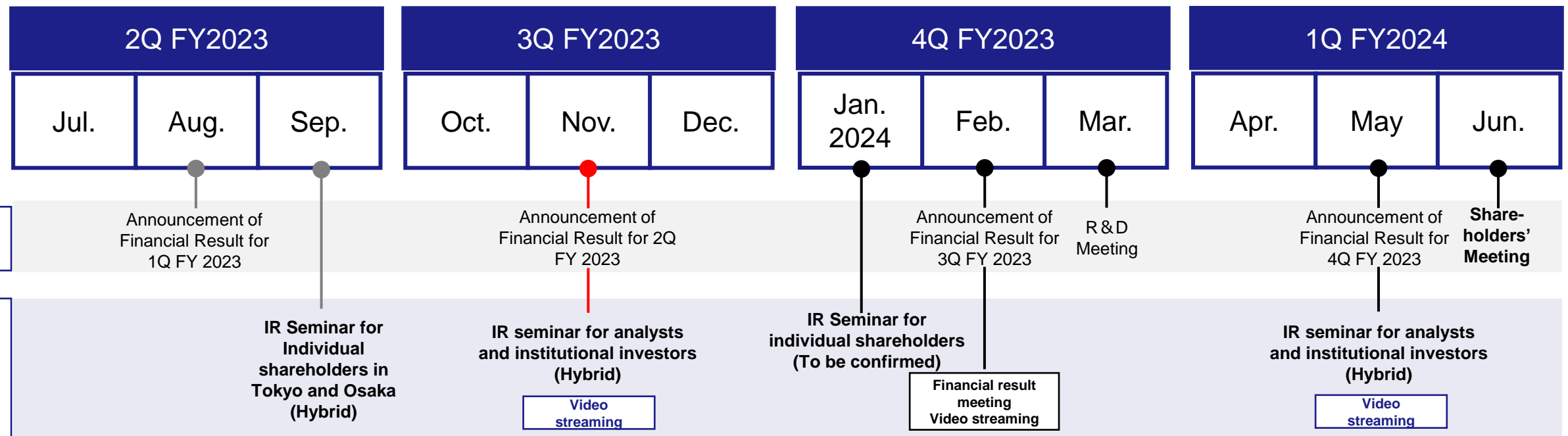
**KIDS WELL, ALL WELL**



# IR Strategies

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

### <Annual IR Schedule>



Actively join IR events for company briefing

Continuing timely video distribution at the time of financial results and press releases

# **KIDS WELL, ALL WELL**

**All for Kids, Kids for All**



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



# All for Kids, Kids for All

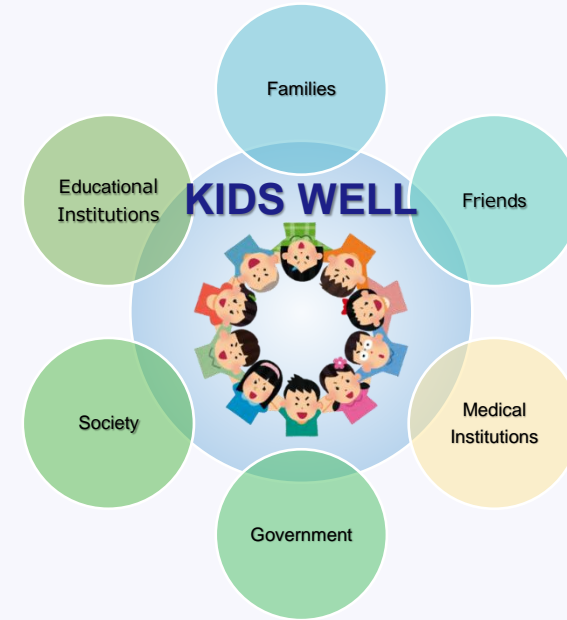
## KIDS WELL, ALL WELL

### Focus areas

Pediatric diseases including juvenile diseases, intractable & rare disease

### Business Direction

Targeting diseases which has less accessibility for sufficient medical treatment



## 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.



## Shinya Kurebayashi President & CEO



Jun. 2004	Massachusetts Institute of Technology, MSc, Physics
Apr.2004	Joined Goldman Sachs Japan. Worked in Investment Banking Div. at Goldman Sachs Japan and involved in M&A, IPOs.
Aug. 2009	Joined Morgan Stanley (Mitsubishi UFJ Morgan Stanley Securities) and involved in investing banking
Oct. 2014	Jointed ImPACT of Cabinet Office
Sept. 2015	Joined Advanced Cell Technology and Engineering LTD (ACTE) as Business Administration Officer
Mar. 2019	Joined Kidswell Bio Corporation (f/k/a Gene Techno Science Co., Ltd.) as Corporate Officer, Chief Business Officer
Jun. 2023	Appointed as President & CEO

Directors	President & CEO	Shinya Kurebayashi	Formerly worked at Goldman Sachs Japan, Morgan Stanley and Advanced Cell Technology and Engineering Ltd.
	Board Director	Masayuki Kawakami	Formerly worked at FUJIFILM Corp. and FUJIFILM Pharmaceuticals USA
	Outside Director	Norikazu Eiki	Former Chairman of Bayer Japan
Corporate Officers	Chief Communication Officer (CCO)	Shinya Kurebayashi	
	Chief Operating Officer (COO) Chief Development Officer (CDO)	Masayuki Kawakami	
	Chief Scientific Officer (CSO)	Yasuyuki Mitani	Formerly worked at Astellas Pharma Inc.
	Chief Manufacturing Officer (CMfO)	Munehika Sakabe	Formerly worked at FUJIFILM Corp.
	Chief Administration Officer (CAO)	Yasuo Sakae	Formerly worked at Astellas Pharma Inc.

**KWB is a unique bio-venture that established stable business foundation by biosimilar business and promote investment in R&D activities for further growth**

**Stability**

**Biosimilar Business**

**Stable Business Foundation**

**Income from launched four BS products  
(Received Manufacturing and Sales  
Approval for GBS-010)**

**Growth Potential**

**Cell Therapy Business  
(Regenerative Medicine)**

**Remarkable Growth Foundation**

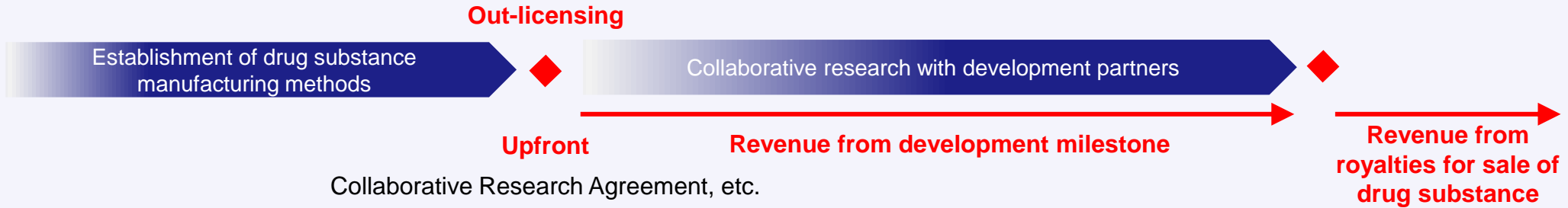
**Accelerating development of cell therapy  
products with SHED  
(Start clinical research for cerebral palsy)**

Aiming for collaboration with development partners (pharmaceutical companies, etc.), from efficient development investment to revenue

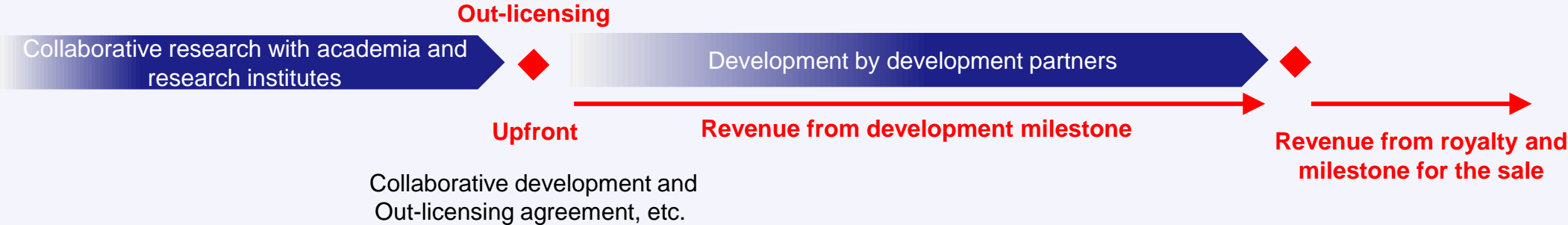


\* General drug development flow

## Biosimilar Business



## Cell Therapy Business



Note) The above figure is an image of revenue model. KWB will proceed an appropriate development structure according to development pipeline.

## Cell Therapy Business: High-risk high return revenue model Biosimilar Business: Low-risk middle return revenue model

