

# FY2022 Financial Results

May 10, 2023

Shionogi & Co., Ltd.



SHIONOGI

# Agenda

- 1. Overview of FY2022 Financial Results (P.3-12)**
- 2. Actions and Financial Forecasts in FY2023 (P.13-28)**
- 3. Shareholder Return (P.29-30)**

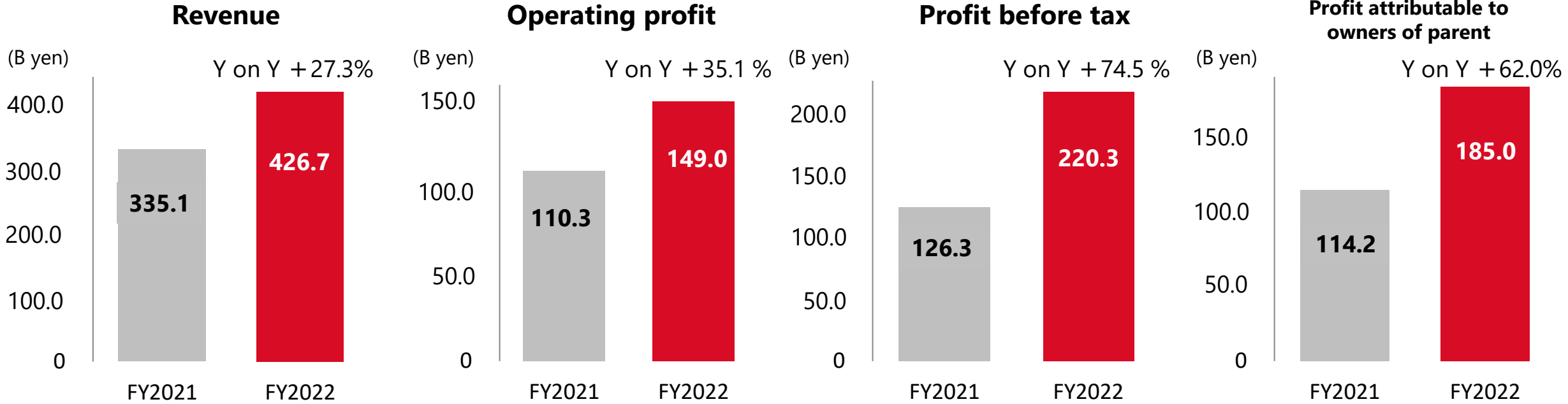
# 1. Overview of FY2022 Financial Results

# Financial Highlights

## Revenue and all profit categories exceeded record highs

- ◆ Revenue : **426.7 B yen** ( 420.2 B yen : FY2001)
- ◆ Profit before tax : **220.3 B yen** ( 174.0 B yen : FY2018)
- ◆ Operating profit : **149.0 B yen** ( 145.1 B yen : FY2018)
- ◆ Profit attributable to owners of parent : **185.0 B yen** ( 137.2 B yen : FY2018)

( ) indicate record high performance



# Financial Results

(Unit: B yen)

	FY2022			FY2021		Y on Y	
	Forecasts revised on Jan.30	Results	Achievement (%)	Results	Change (%)	Change	
Revenue	421.0	<b>426.7</b>	<b>101.4</b>	335.1	<b>27.3</b>	91.5	
Operating profit	147.0	<b>149.0</b>	<b>101.4</b>	110.3	<b>35.1</b>	38.7	
Core operating profit*	144.5	<b>158.5</b>	<b>109.7</b>	110.6	<b>43.3</b>	47.9	
Profit before tax	210.0	<b>220.3</b>	<b>104.9</b>	126.3	<b>74.5</b>	94.1	
Profit attributable to owners of parent	170.0	<b>185.0</b>	<b>108.8</b>	114.2	<b>62.0</b>	70.8	

- **Year-on-year increases in revenue and all profit categories**

- The commercialization of Xocova (ensitrelvir) and the growth of the base business contributed
- Invested over 100 billion yen in R&D, the largest amount ever

- **Exceeded revised forecasts for all items**

Exchange Rate (average)	FY2022 Forecasts (Jan. 30)	FY2022 results
USD (\$) – JPY (¥)	<b>135</b>	<b>135.51</b>
GBP (£) – JPY (¥)	<b>162</b>	<b>163.22</b>
EUR (€) – JPY (¥)	<b>140</b>	<b>140.99</b>

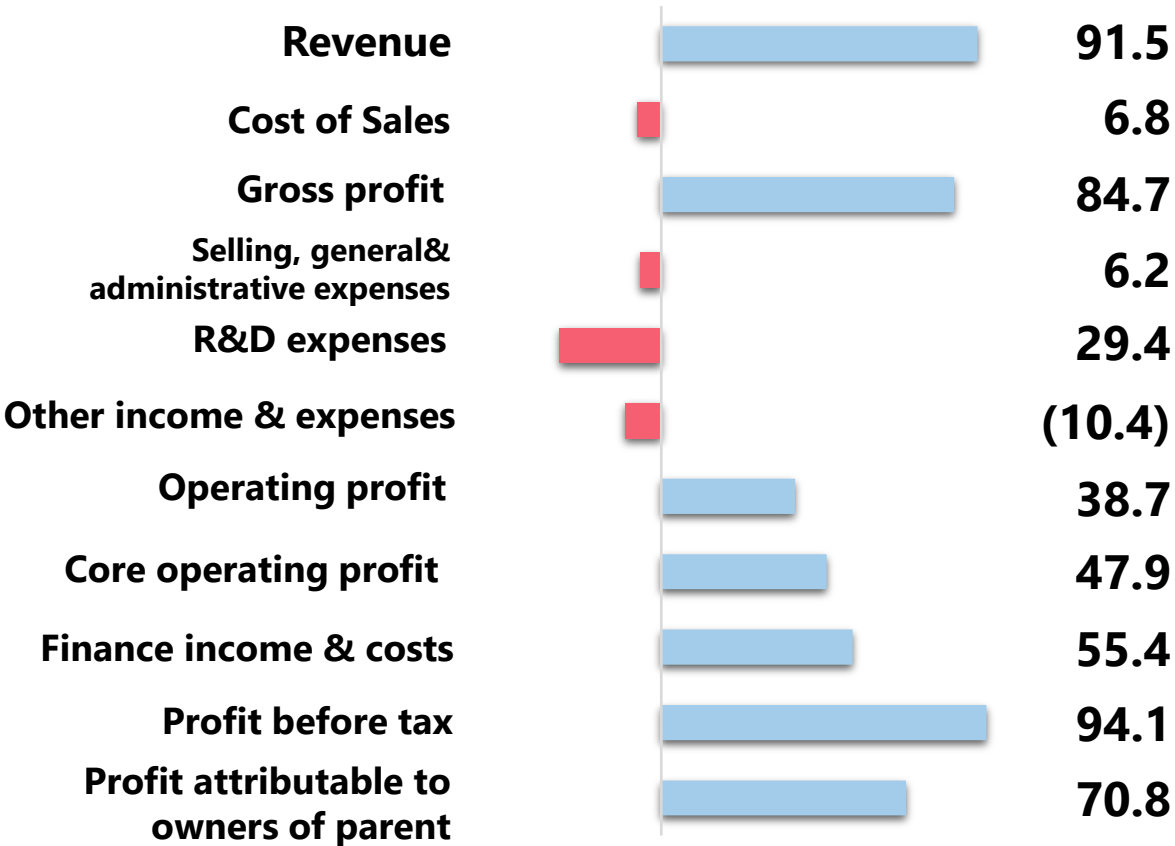
# Statement of Profit or Loss

(Unit: B yen)

	FY2022		Achievement (%)	FY2021		Y on Y	
	Forecasts Jan.30	Results		Results	Change (%)	Change	
Revenue	421.0	<b>426.7</b>	<b>101.4</b>	335.1	<b>27.3</b>	91.5	
Cost of Sales	15.7 66.0	<b>14.6</b> <b>62.2</b>	<b>94.3</b>	16.5 55.4	<b>12.3</b>	6.8	
Gross profit	355.0	<b>364.4</b>	<b>102.7</b>	279.7	<b>30.3</b>	84.7	
Selling, general & administrative expenses, R&D expenses total	48.9 206.0	<b>47.8</b> <b>203.9</b>	<b>99.0</b>	50.2 168.2	<b>21.2</b>	35.6	
Selling, general & administrative expenses	24.5 103.0	<b>23.8</b> <b>101.5</b>	<b>98.5</b>	28.4 95.2	<b>6.6</b>	6.2	
R&D expenses	24.5 103.0	<b>24.0</b> <b>102.4</b>	<b>99.4</b>	21.8 73.0	<b>40.3</b>	29.4	
Other income & expenses	(2.0)	<b>(11.5)</b>	-	(1.2)	-	(10.4)	
Operating profit	34.9 147.0	<b>34.9</b> <b>149.0</b>	<b>101.4</b>	32.9 110.3	<b>35.1</b>	38.7	
Core operating profit	34.3 144.5	<b>37.1</b> <b>158.5</b>	<b>109.7</b>	33.0 110.6	<b>43.3</b>	47.9	
Finance income & costs	63.0	<b>71.3</b>	<b>113.2</b>	16.0	<b>347.0</b>	55.4	
Profit before tax	49.9 210.0	<b>51.6</b> <b>220.3</b>	<b>104.9</b>	37.7 126.3	<b>74.5</b>	94.1	
Profit attributable to owners of parent	170.0	<b>185.0</b>	<b>108.8</b>	114.2	<b>62.0</b>	70.8	

# Statement of Profit or Loss (Y on Y)

-50 0 50 100 (Unit: B yen)



Decrease factors

Increase factors

## Main Variation Factors (Y on Y\*)

- **Revenue**
  - Increase: COVID-19 related products  
Overseas subsidiaries/export
  - Decrease: Prescription drugs
- **Cost of Sales**
  - Increase : Increased revenue and changes in product mix
- **Selling, general & administrative expenses**
  - Increase: Expenses associated with prescription drugs sales, including Xocova, pre-launch expenses for global
- **R&D expenses**
  - Increase: Investment in R&D activities including COVID-19 related projects
- **Other income & expenses**
  - Decrease in other income
    - : Impairment due to revision of development plan of Zatulmilast (BPN14770) in Alzheimer's disease
- **Finance income & costs**
  - Increase in income
    - : Increased dividend reflecting ViiV's strong business

# Revenue by Segment

(Unit: B yen)

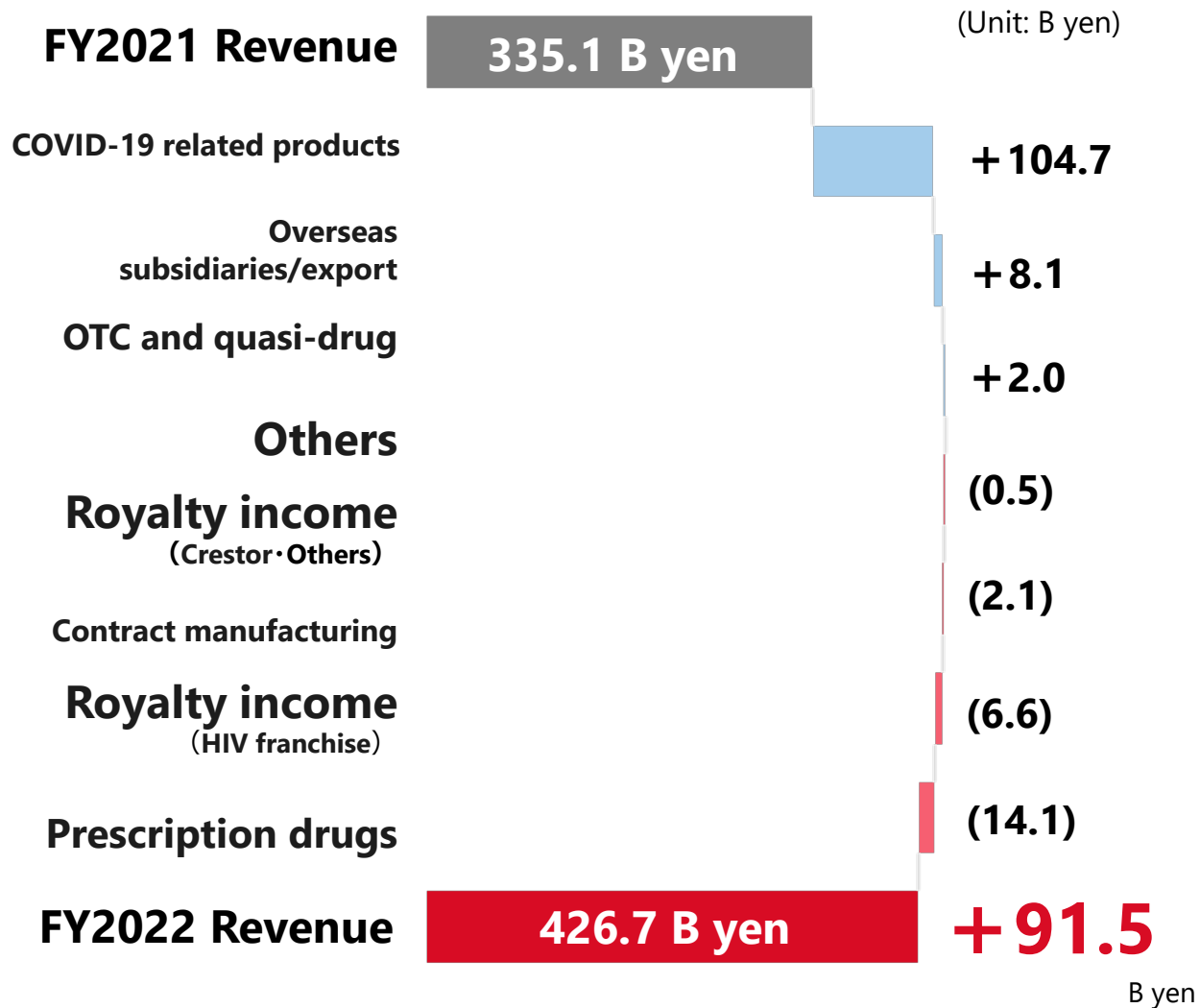
	FY2022			FY2021	Y on Y	
	Forecasts Revised on Jan. 30	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	76.4	<b>75.0</b>	<b>98.2</b>	89.1	<b>(15.8)</b>	<b>(14.1)</b>
Overseas subsidiaries/export	39.3	<b>42.5</b>	<b>108.1</b>	34.4	<b>23.7</b>	<b>8.1</b>
Shionogi Inc. (US)	14.4	<b>15.4</b>	<b>107.0</b>	13.8	<b>12.2</b>	<b>1.7</b>
Fetroja	-	<b>10.0</b>	-	6.2	<b>59.5</b>	<b>3.7</b>
Ping An-Shionogi*/C&O	10.4	<b>12.0</b>	<b>115.3</b>	10.2	<b>17.7</b>	<b>1.8</b>
Shionogi B.V. (EU)	8.6	<b>9.1</b>	<b>105.6</b>	5.0	<b>81.4</b>	<b>4.1</b>
Contract manufacturing	14.8	<b>15.3</b>	<b>103.8</b>	17.4	<b>(12.0)</b>	<b>(2.1)</b>
OTC and quasi-drug	13.2	<b>13.1</b>	<b>99.2</b>	11.2	<b>17.7</b>	<b>2.0</b>
Royalty income	166.0	<b>174.7</b>	<b>105.2</b>	181.3	<b>(3.6)</b>	<b>(6.6)</b>
HIV franchise	159.9	<b>168.5</b>	<b>105.3</b>	174.0	<b>(3.2)*<sup>3</sup></b>	<b>(5.5)</b>
Crestor	1.3	<b>1.3</b>	<b>100.0</b>	1.2	<b>15.4</b>	<b>0.2</b>
Others	4.8	<b>4.9</b>	<b>102.9</b>	6.1	<b>(20.0)</b>	<b>(1.2)</b>
COVID-19 related products <sup>*2</sup>	110.0	<b>104.7</b>	<b>95.2</b>	-	-	<b>104.7</b>
Others	1.2	<b>1.3</b>	<b>108.2</b>	1.8	<b>(28.8)</b>	<b>(0.5)</b>
<b>Total</b>	<b>421.0</b>	<b>426.7</b>	<b>101.4</b>	<b>335.1</b>	<b>27.3</b>	<b>91.5</b>

\* OTC and quasi-drugs also include in revenue of joint venture \*2 Revenue from Xocova and S-268019

<sup>\*3</sup> Received royalty income from the conclusion of dolutegravir patent license agreement in FY2021



# Revenue by Segment (Y on Y)



## Main Variation Factors (Y on Y\*)

- COVID-19 related products**
  - Increase: Purchase of 2 million courses of Xocova by the Japanese government
  - : Sales of Xocova in Japan through general distribution
  - ※**Special Notes for 4Q**
- Overseas subsidiaries/export**
  - Increase: Sales of cefiderocol (Fetroja, Fetcroja)
- Royalty income**
  - HIV franchise
    - › Increase: Strong sales of ViiV's HIV franchise
    - › Decrease: Income from settlement agreement in prior year
    - ⇒ Excluding the one-time factor and the impact of exchange rates, royalty income from the HIV franchise grew 15% Y on Y
- Prescription drugs**
  - Increase: Sales of Intuniv and Vyvanse
  - Decrease: Sales of Cymbalta· Returns of Xofluza and Rapiacta

# Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022			FY2021		Y on Y	
	Forecasts Full year (Jan 30)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Intuniv	20.0	19.2	96.1	16.4	17.0	2.8	
Vyvanse	1.3	1.4	112.3	0.8	81.2	0.6	
Infectious disease drugs	8.8	7.4	84.7	11.8	(37.2)	(4.4)	
Influenza franchise	0.1	(1.1)*	-	3.1	-	(4.2)	
Cymbalta	6.1	5.4	89.2	15.9	(65.8)	(10.5)	
OxyContin franchise	4.5	4.4	98.8	4.8	(7.6)	(0.4)	
Symproic	3.4	3.4	100.1	2.7	28.1	0.7	
Actair	0.6	0.5	93.4	0.5	8.8	0.0	
Mulpleta	0.1	0.1	81.6	0.1	(16.5)	(0.0)	
Pirespa	2.4	2.5	106.8	3.8	(33.6)	(1.3)	
Others	29.4	30.6	104.1	32.4	(5.5)	(1.8)	
Crestor	3.9	4.1	104.1	5.9	(30.7)	(1.8)	
<b>Prescription drugs</b>	<b>76.4</b>	<b>75.0</b>	<b>98.2</b>	<b>89.1</b>	<b>(15.8)</b>	<b>(14.1)</b>	

<Products categorized as infectious disease drugs>

- Xofluza
- Rapiacta
- Brightpoc Flu•Neo



Influenza franchise

- FINIBAX
- Flumarin
- Flomox

- Shiomarin
- Vancomycin
- Baktar

- Flagyl
- ISODINE

\* Sales of 4.2 billion yen recorded for influenza family in April-December. Approximately 5.3 B yen worth of products that expire this year were returned in the second quarter.

# FY2022 Results for Medium-Term Business Plan STS2030 KPIs

	KPI	FY2019 (Result)	FY2020 (Result)	FY2022 (Target)	FY2022 (Results)		FY2024	FY2030
Growth indications	Revenues	333.4 B yen	297.2 B yen	400.0 B yen	<b>426.7 B yen</b>	Achieved	500.0 B yen	600.0 B yen
	Core operating profit*	127.4 B yen	94.0 B yen	120.0 B yen	<b>158.5 B yen</b>	Achieved	150.0 B yen	200.0 B yen
	Core operating profit margin	38.2%	31.6%	Over 30%	<b>37.1%</b>	Achieved	Over 30%	-
	Overseas revenue ratio (excluding RYT)	18.5%	16.2%	Over 25%	<b>16.5%</b>	Unachieved	Over 50%	-
	Internally-discovered pipeline ratio	67%	71%	Over 60%	<b>61%</b>	Achieved	Over 60%	-
Shareholder return indications	EPS	395.71yen	365.03yen	Over 370 yen	<b>621.31yen</b>	Achieved	Over 480 yen	-
	DOE	4.0%	4.1%	Over 4%	<b>3.9% (planned)</b>	Unachieved	Over 4%	-
	ROE	15.5%	13.9%	Over 13%	<b>17.8%</b>	Achieved	Over 15%	-

# Results for FY2022

## Progress of COVID-19 projects

- Domestic commercialization of Xocova, building foundations for global expansion, progress in trials
- Domestic approval application for COVID-19 vaccine

## A paradigm shift in the HIV franchise

- Extension of HIV franchise due to rapid growth of long-acting formulations

## Development of growth drivers

- Shifted resources from COVID-19 to other growth drivers
- Progressed 6 pipeline products into the next stage of clinical development\*

**Exceeded record high performance  
and built a foundation for further growth**

## **2. Actions and Financial Forecasts in FY2023**

# Direction for FY2023

## Accelerating global expansion with the new infectious disease products created in FY2022

### Top-line growth through global sales expansion

- Expand sales of Xocova in Japan and Asia
- Promoting initiatives in the infectious disease area
  - Development of government stockpiles and subscription model
  - Building a foundation for global supply

### Establishment of growth drivers that can be deployed globally

- Aggressive investment to advance global self-developed products
- Strengthening in-licensing to expand development and product portfolio
- Domestic launch and global expansion of vaccines

**Transform into a company that can expand globally on its own**

# Earnings Forecast

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	<b>450.0</b>	<b>217.0</b>	426.7	5.5	23.3
Operating profit	<b>150.0</b>	<b>80.5</b>	149.0	0.7	1.0
Core operating profit*	<b>150.0</b>	<b>80.5</b>	158.5	(5.4)	(8.5)
Profit before tax	<b>192.5</b>	<b>98.0</b>	220.3	(12.6)	(27.8)
Profit attributable to owners of parent	<b>155.0</b>	<b>78.0</b>	185.0	(16.2)	(30.0)

- **Achieved higher sales and profits due to top-line growth from expanding global sales of infectious diseases products**
- **Aggressive investment for global expansion and establishment of growth drivers**

Exchange Rate (average)	FY2023 Forecasts	FY2022 Results
USD (\$) – JPY (¥)	<b>130</b>	<b>135.51</b>
GBP (£) – JPY (¥)	<b>160</b>	<b>163.22</b>
EUR (€) – JPY (¥)	<b>140</b>	<b>140.99</b>

# Forecast: Revenue by Segment

(Unit: B yen)

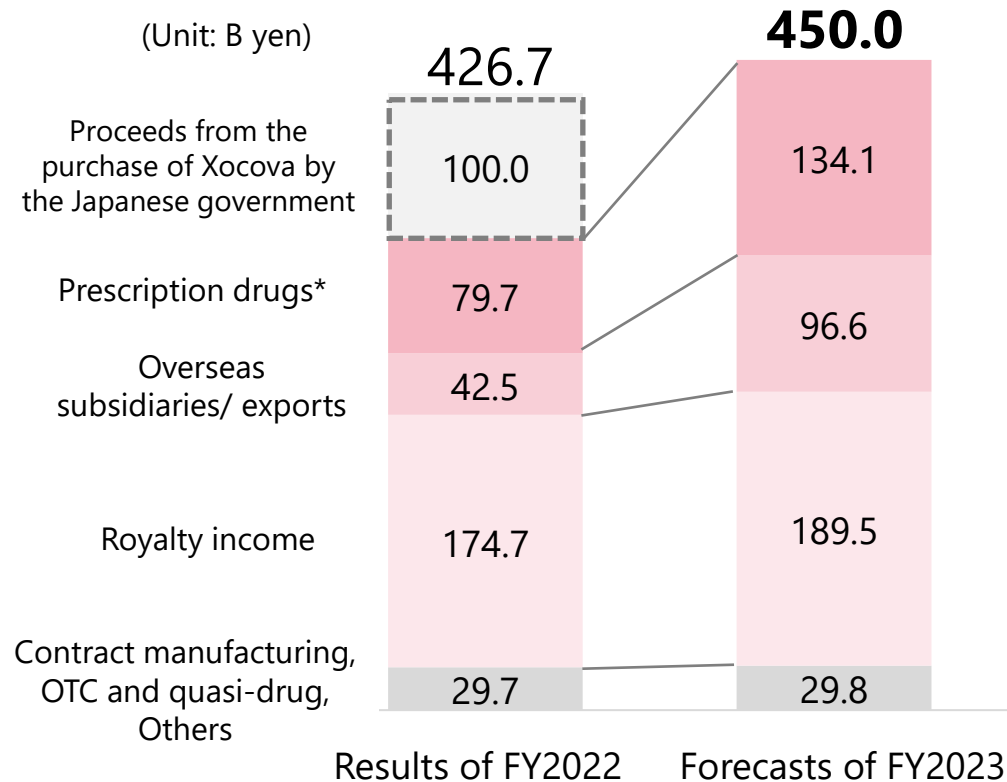
	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Prescription drugs	134.1	87.4	179.7**	(25.4)	(45.6)
Overseas subsidiaries/export	96.6	28.0	42.5	127.3	54.1
Shionogi Inc. (US)	13.6	6.7	15.4	(11.7)	(1.8)
Shionogi BV (EU)	11.5	5.4	9.1	27.2	2.5
Ping An-Shionogi* /C&O	58.0	13.2	12.0	384.8	46.0
Others	13.4	2.7	6.0	122.9	7.4
Contract manufacturing	13.8	7.3	15.3	(10.1)	(1.5)
OTC and quasi-drug	15.0	6.8	13.1	14.2	1.9
Royalty income	189.5	86.9	174.7	8.5	14.8
HIV franchise	185.0	86.0	168.5	9.8	16.5
Others	4.5	0.9	6.2	(27.4)	(1.7)
Others	1.0	0.5	1.3	(21.6)	(0.3)
<b>Total</b>	<b>450.0</b>	<b>217.0</b>	<b>426.7</b>	<b>5.5</b>	<b>23.3</b>



# Global Top-line Growth

Achieve top-line growth through our own sales of Xocova in Japan, expansion overseas, and growth of base business

## Revenue Forecast by Segment ( Y on Y )



- **Forecast includes 105.0 B yen in Xocova and COVID-19 vaccine sales**
- **Prescription drugs : + 54.4 B yen**
  - Xocova, COVID-19 vaccine, Influenza franchise
- **Overseas subsidiaries/ exports : + 54.1 B yen**
  - Xocova : China, South Korea, Taiwan
  - Cefiderocol
- **Royalty income : + 14.8 B yen**

# Xocova (Ensitrelvir): Global Expansion\*

In fiscal 2023, we seek to establish clear growth in Japan and obtain approval and start commercialization in Asia, mainly in China and Korea

## Japan : Start of general distribution and transition to category 5 infectious diseases

- Creating an environment where everyone can receive early diagnosis and early treatment, similar to influenza
- In discussion with PMDA to change from emergency approval to full approval
- Started Phase 3 pediatric trial (IND submission, April 2023)
- Communicating the significance and value of antiviral drug administration
  - Rapid elimination of infective virus due to strong antiviral effect
  - Early improvement of COVID-19 symptoms
  - Reducing of the risk of Long COVID manifestation (Continuing evaluation)

## US/UK,EU

- Two Global Phase 3 trials supported by NIH\*<sup>2</sup> progressing smoothly
- Started SCORPIO-PEP\*<sup>3</sup> trial to verify post-exposure prophylaxis (IND submission, April 2023)
- Receives U.S. FDA Fast Track Designation

## China : Preparing to apply

- Preliminary materials related to application have been submitted, and inquiries from authorities are being addressed
- Establishing internal and external systems necessary for in-house sales
  - Concluding license agreements with partner companies for import/distribution and promotion
- Establishing production system

## Korea : Submitted an approval application

- Under MFDS\*<sup>4</sup> review for approval
- ILDONG will continue discussions with the Korean government and regulatory authorities regarding the distribution method after obtaining approval
- Currently transferring formulation technology for local production

## Taiwan/Other Asian countries

- Taiwan: Taiwan Shionogi filed for EUA
- Conducted partnering discussions in other Asian countries

# Xocova (Ensitrelvir): Latest Data\* from Phase 3 Part of Phase 2/3 Trial

**Positive data, attributed to strong antiviral effects, continue to be generated**

## Reduced risk of Long COVID manifestation\*<sup>2</sup>

- Significantly reduced risk of manifestation of Long COVID in severely symptomatic patients versus placebo
  - 45% reduction in the proportion of patients with longer-term presence of any of the 14 symptoms characteristic of COVID-19
  - 33% reduction in the proportion of patients presenting with the four most commonly reported post-acute neurological symptoms

Mukae H. et al., Precision Medicine 2023.6(4):291.

## Regarding viral rebound and symptom recurrence\*<sup>3</sup>

- Symptom recurrence was rare and was not associated with viral RNA rebound
- Although RNA rebound was observed in a small number of patients, there was only one case of (1/310) low level viral titer positivity in follow up, suggesting no concerns for infectivity or transmission.

The 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID)

# Vaccine Business: Building a New Business Foundation

Establish vaccines as a medium- to long-term growth driver, including domestic launch of S-268019

## COVID-19 vaccine: S-268019

- Under review by MHLW and PMDA for approval
- Accelerate preparations for domestic supply
- Efforts toward LCM to maximize value
  - Adolescents, school children, adult booster (4th vaccination)
  - Omicron strains
  - Expression of Interest (EoI) filed with WHO for S-268019 to be placed on the Emergency Use List (EUL)

## Establishment of a production system for recombinant protein vaccines

- Initial supply from UMN Pharma
- Ongoing efforts toward mass production at UNIGEN
- Partnering for multiple production options

## Expansion of vaccine business

- Development of influenza vaccines
- Building a foundation for the development of nasal vaccines and universal vaccines

# Cefiderocol: Countermeasure against AMR\*, an issue that must be addressed on a global scale

## Accelerate advanced actions for a sustainable acute infectious disease business model

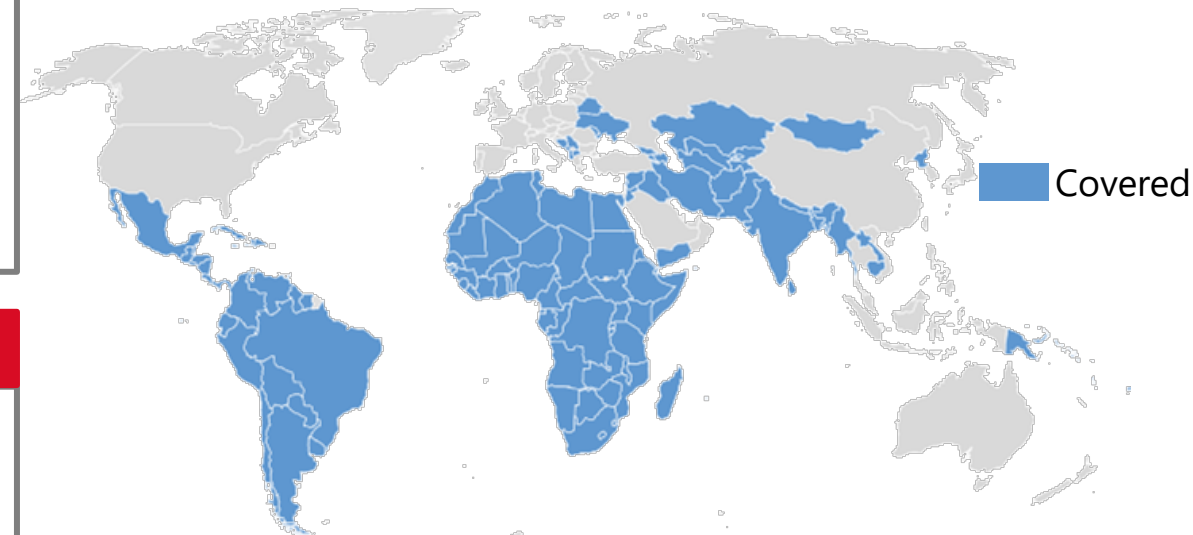
### Actions to improve access

- Expand launched countries and ensure broader understanding of appropriate use in already launched countries
- Alliance established to work towards in 135 countries including LMICs\*<sup>4</sup>
  - Execution of a collaboration agreement with GARDP and CHAI\*<sup>5</sup> (June 2022)
- Promote pull incentives including subscription-type reimbursement models

### Approaches to optimize antibiotic use

- Encourage medical institutions to adhere to Antibiotic Stewardship\*<sup>6</sup>
- Maximize value of real world data evidence: PROVE trial topline results\*<sup>7</sup>
- Cefiderocol recommendation in NICE antimicrobial health technology evaluation guidance\*<sup>8</sup> (August 2022)

### Countries covered by partnerships with GARDP\*<sup>2</sup> and CHAI\*<sup>3</sup>



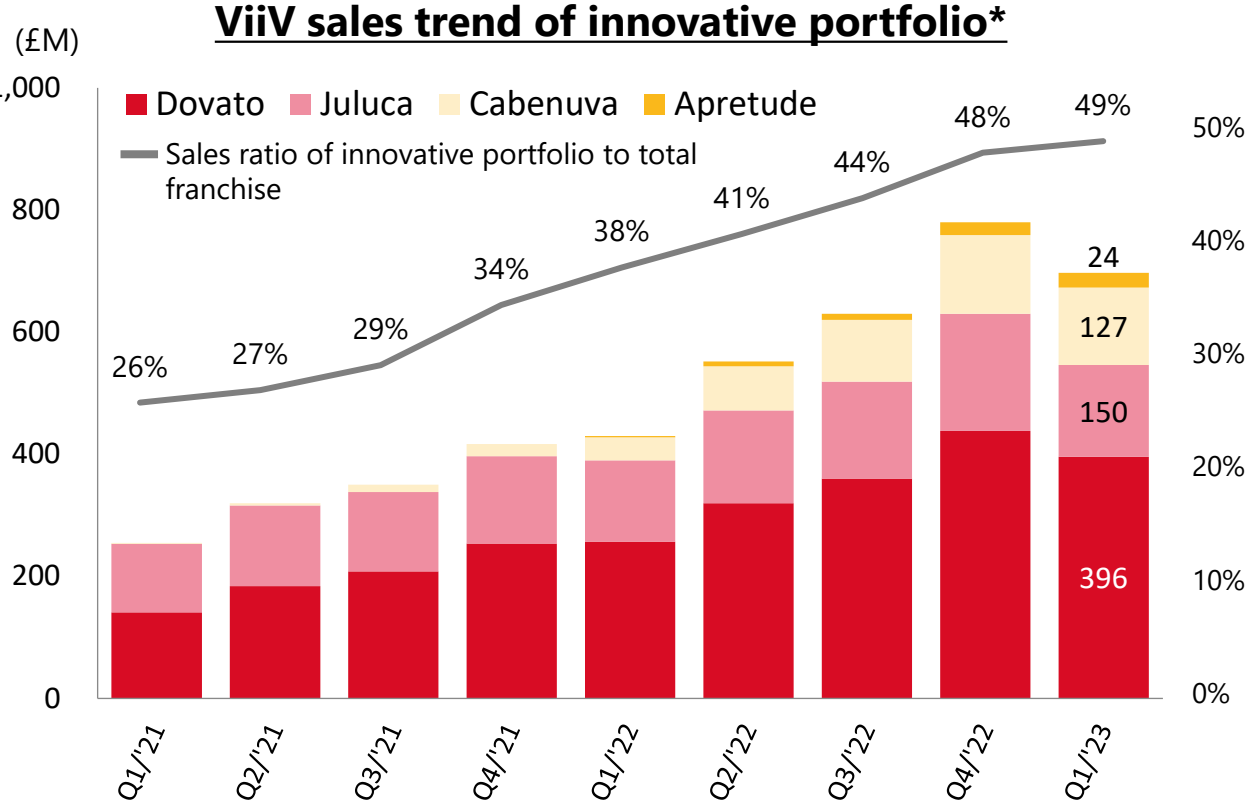
\* Antimicrobial resistance \*<sup>2</sup> Global Antibiotic Research and Development \*<sup>3</sup> Clinton Health Access Initiative \*<sup>4</sup> Low- and middle-income countries

<sup>5</sup> [Press release on June 15, 2022](#) \*<sup>6</sup> [Core Elements of Antibiotic Stewardship | Antibiotic Use | CDC](#) \*<sup>7</sup> [Press release on April 17, 2023](#)

<sup>8</sup> [Antimicrobial health technology evaluation guidance](#)

# Progress of HIV Business by ViiV

Paradigm shift due to growth of oral 2-drug regimens and LA formulations and accelerating of next-generation pipeline development



## Further growth of top line

- Dovato: Driving growth in overall HIV franchise sales
- Cabenuva: About 90% of clinical trial participants prefer Cabenuva therapy over daily oral pills\*<sup>2</sup>
- Apretude: Growing sales in US with launch to follow in Europe (Expected EMA approval in late 2023)

## Development of next-generation pipeline

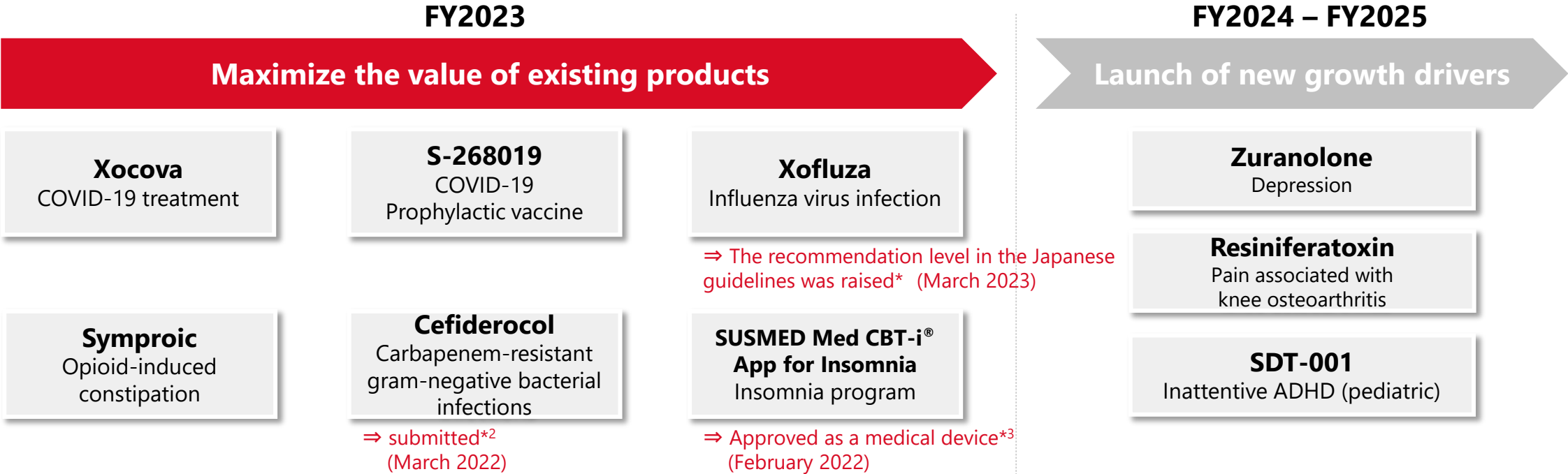
- S-365598\*<sup>3</sup>: Phase 1 trial ongoing
- N6LS (combination candidate for ultra LA): Expect to begin a phase 2b trial

\* Source: GSK financial statement \*<sup>2</sup> [GSK press release](#) \*<sup>3</sup> ViiV development numberVH4524184



# Direction of Domestic Business

Continue to expand sales and portfolio for sustainable growth in focus areas



## Introductions of new growth drivers

Continue aggressive M&A and in-licensing negotiations centered on products and compounds that contribute to short-term sales

\* [New recommendations for the use of Xofluza by the Japanese Association for Infectious Diseases](#) \*2 [SHIONOGI press release](#) \*3 [SUSMED press release](#)

# Milestones of Major Development Products

## Selection and concentration on growth drivers addressing unmet medical needs

Disease area	Pipeline	Indication	FY2022	FY2023	FY2024
Infection	<b>Olorofim</b>	Invasive aspergillosis	Phase 3	Phase 3 Completion of case registration (4Q)	
	<b>S-337395</b>	RSV infections	Phase 1	Phase 1 topline results	
	<b>S-892216</b>	COVID-19	Phase 1	Phase 1 topline results	
Psychiatry/ Nervous/Pain	<b>Zuranolone</b>	Depression	Phase 3	Phase 3 topline results (3Q) Submission (4Q)	
	<b>Resiniferatoxin</b>	Pain associated with knee osteoarthritis	Phase 3	Submission (4Q)	
	<b>SDT-001</b>	ADHD	Phase 3	Submission	
	<b>Zatolmilast</b>	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline results (2Q) Submission (3Q)	
	<b>S-151128</b>	Chronic pain	Phase 1	Phase 1 topline results	
New growth area	<b>S-309309</b>	Obesity	Phase 2	Phase 2 topline results (4Q)	
	<b>S-531011</b>	Solid tumor	Phase 1b/2	Phase 2 (4Q)	
	<b>Redasemtide</b>	Dystrophic epidermolysis bullosa	Phase 2	Submission (3Q)	
Acute cerebral infarction		Phase 2b			



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(Unit: B yen)

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Profit before tax	<b>192.5</b>	<b>98.0</b>	220.3	(12.6)	(27.8)
Profit attributable to owners of parent	<b>155.0</b>	<b>78.0</b>	185.0	(16.2)	(30.0)

- **Achieved higher sales and profits due to top-line growth from expanding global sales of infectious diseases**
- **Aggressive investment for global expansion and establishment of growth drivers**

Exchange Rate (average)	FY2023 Forecasts	FY2022 results
USD (\$) – JPY (¥)	<b>130</b>	<b>135.51</b>
GBP (£) – JPY (¥)	<b>160</b>	<b>163.22</b>
EUR (€) – JPY (¥)	<b>140</b>	<b>140.99</b>

# Forecast: Statement of Profit and Loss

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	450.0	217.0	426.7	5.5	23.3
Cost of Sales	15.3 69.0	14.5 31.5	14.6 62.2	10.8	6.8
Gross profit	381.0	185.5	364.4	4.5	16.6
Selling, general& administrative expenses, R&D expenses total	50.9 229.0	47.7 103.5	47.8 203.9	12.3	25.1
Selling, general& administrative expenses	28.9 130.0	24.9 54.0	23.8 101.5	28.1	28.5
R&D expenses	22.0 99.0	22.8 49.5	24.0 102.4	(3.3)	(3.4)
Other income & expenses	(2.0)	(1.5)	(11.5)	-	9.5
Operating profit	33.3 150.0	37.1 80.5	34.9 149.0	0.7	1.0
Core operating profit	33.3 150.0	37.1 80.5	37.1 158.5	(5.4)	(8.5)
Finance income & costs	42.5	17.5	71.3	(40.4)	(28.8)
Profit before tax	42.8 192.5	45.2 98.0	51.6 220.3	(12.6)	(27.8)
Profit attributable to owners of parent	155.0	78.0	185.0	(16.2)	(30.0)

# Forecast: Revenue by Segment

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
<b>Prescription drugs</b>	<b>134.1</b>	<b>87.4</b>	179.7	(25.4)	(45.6)
<b>Overseas subsidiaries/export</b>	<b>96.6</b>	<b>28.0</b>	42.5	127.3	54.1
Shionogi Inc. (US)	13.6	6.7	15.4	(11.7)	(1.8)
Shionogi B.V. (EU)	11.5	5.4	9.1	27.2	2.5
Ping An-Shionogi* /C&O	58.0	13.2	12.0	384.8	46.0
Others	13.4	2.7	6.0	122.9	7.4
<b>Contract manufacturing</b>	<b>13.8</b>	<b>7.3</b>	15.3	(10.1)	(1.5)
<b>OTC and quasi-drug</b>	<b>15.0</b>	<b>6.8</b>	13.1	14.2	1.9
<b>Royalty income</b>	<b>189.5</b>	<b>86.9</b>	174.7	8.5	14.8
HIV franchise	185.0	86.0	168.5	9.8	16.5
Others	4.5	0.9	6.2	(27.4)	(1.7)
<b>Others</b>	<b>1.0</b>	<b>0.5</b>	1.3	(21.6)	(0.3)
<b>Total</b>	<b>450.0</b>	<b>217.0</b>	426.7	5.5	23.3

## Assumptions for forecasts

### • Prescription drugs

- Sales revenue of Xocova and COVID-19 vaccine in Japan included in forecast
- Recorded 100.0 billion yen in income from the purchase of Xocova by the Japanese government in FY2022

### • Overseas subsidiaries/export

- **Shionogi Inc.**
  - > Decrease in sales year-on-year due to change in Osphena sales scheme\*\*
- **Ping An-Shionogi/C&O**
  - > Sales revenue of Xocova in China and South Korea included in forecast
- **Others**
  - > Sales revenue of Xocova in Taiwan included in forecast

# Forecasts: Prescription Drugs in Japan

(Unit: B yen)

	FY2023 Forecasts		FY2022	Y on Y	
	Full year	1H	Results	Change (%)	Change
<b>Infectious disease drugs</b>	<b>65.7</b>	<b>40.0</b>	112.1	(41.4)	(46.4)
Covid-19 related products + Influenza franchise	<b>57.3</b>	<b>35.8</b>	103.6	(44.7)	(46.3)
<b>Cymbalta</b>	<b>4.2</b>	<b>2.1</b>	5.4	(23.5)	(1.3)
<b>OxyContin franchise</b>	<b>4.1</b>	<b>2.1</b>	4.4	(6.6)	(0.3)
<b>Symproic</b>	<b>4.9</b>	<b>2.3</b>	3.4	44.6	1.5
<b>Actair</b>	<b>1.0</b>	<b>0.4</b>	0.5	91.0	0.5
<b>Mulpleta</b>	<b>0.1</b>	<b>0.1</b>	0.1	25.9	0.0
<b>Pirespa</b>	<b>1.9</b>	<b>1.1</b>	2.5	(24.4)	(0.6)
<b>Others</b>	<b>52.1</b>	<b>39.3</b>	51.2*	1.8	0.9
Lump-sum income from transfer of ADHD drug	<b>25.0</b>	<b>25.0</b>	-	-	25.0
<b>Prescription drugs</b>	<b>134.1</b>	<b>87.4</b>	<b>179.7</b>	<b>(25.4)</b>	<b>(45.6)</b>

<Products categorized as infectious disease drugs>

- Xocova
- COVID-19 vaccines

- Xofluza
- Rapiacta
- BrightpocFlu·Neo

- FINIBAX
- Flumarin
- Flomox

- Shiomarin
- Baktar

- Flagyl
- ISODINE

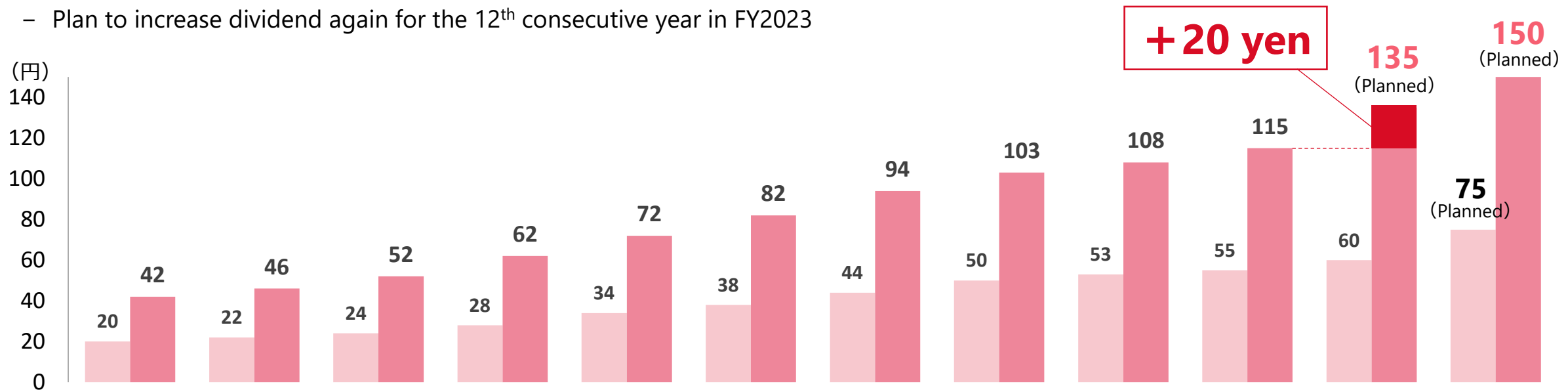


### **3. Shareholder Return**

# Flexible and Prompt Capital Strategy

- **Shareholder return policy through which shareholders can feel our growth**

- Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
- FY2022 is the largest annual dividend increase (+20 yen)
- Plan to increase dividend again for the 12<sup>th</sup> consecutive year in FY2023

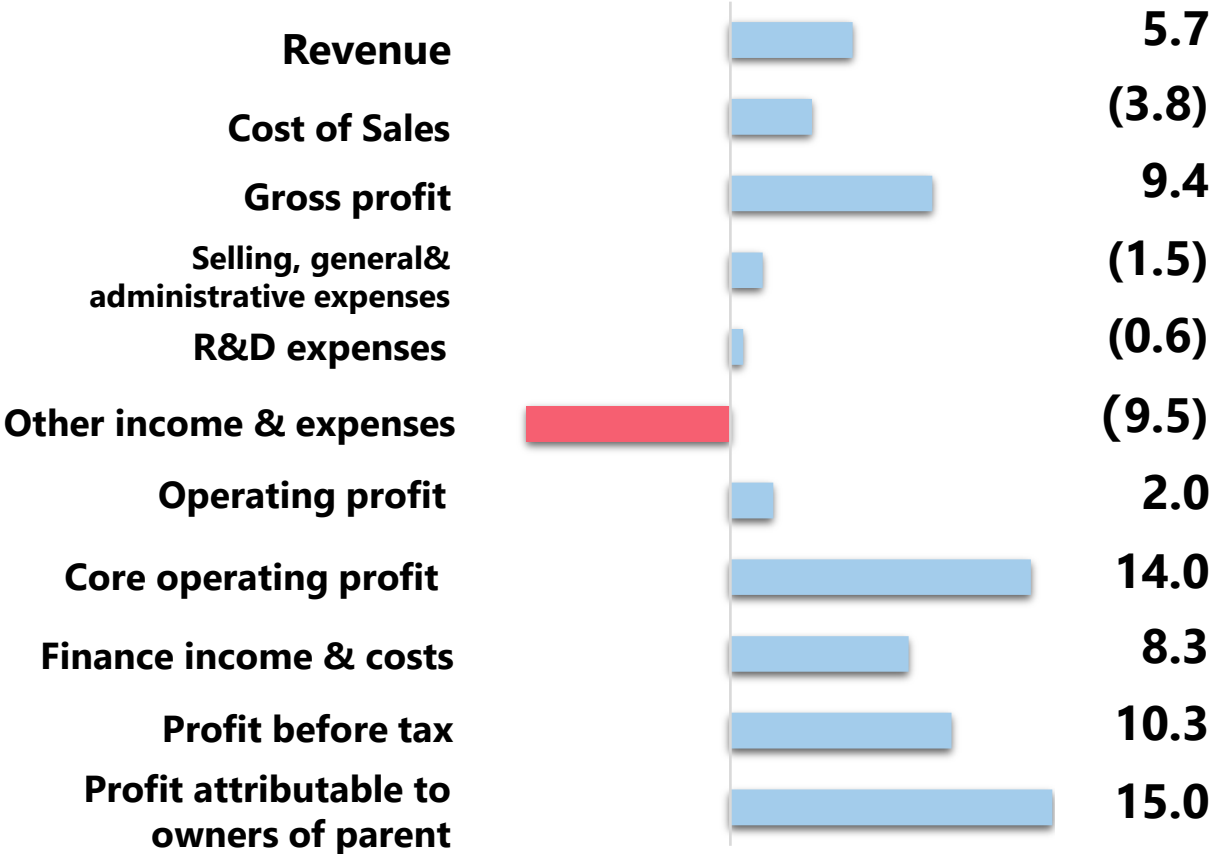


FY	12	13	14	15	16	17	18	19	20	21	22	23	
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	-
	Cancellation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	-
DOE (%)	3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9(planned)	4.0 (expected)	
ROE (%)	17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.5 (expected)	

# Appendix

# Statement of Profit or Loss (Forecast Comparison)

-5      5      10      (Unit: B yen)



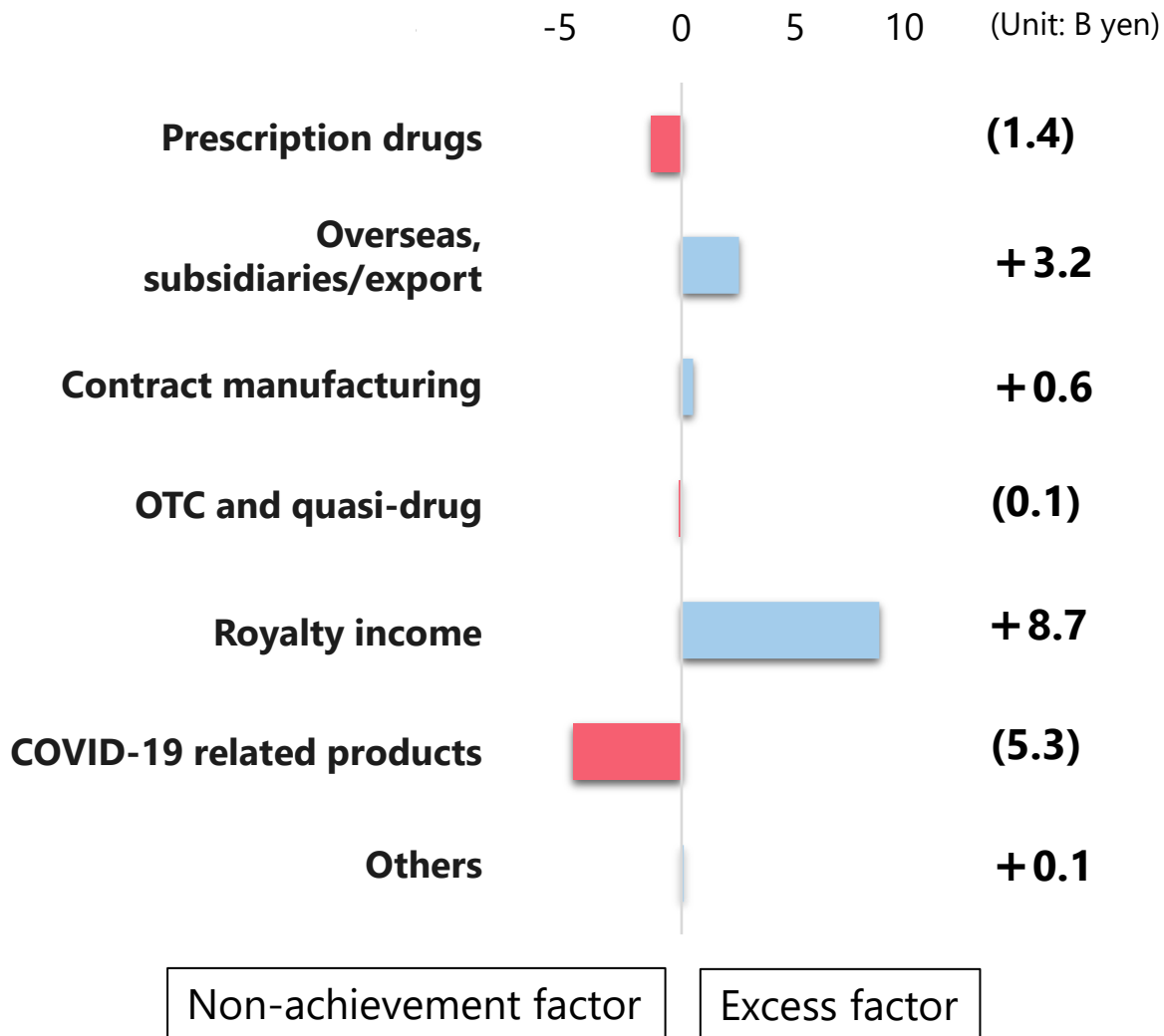
Non-achievement factor      Excess factor

## Main Variation Factors (vs. Forecasts)

- **Revenue**
  - Increase: Overseas subsidiaries/export, Royalty income
- **Cost of Sales**
  - Decrease: Lower product costs through improved manufacturing efficiency
- **Other income & expenses**
  - Decrease in income
    - : Impairment due to revision of development plan of Zatoimilast (BPN14770) in Alzheimer's disease
  - ※Special Notes for 4Q
- **Finance income & costs**
  - Increase in income
    - : Increased dividend reflecting ViiV's strong business



# Revenue by Segment ( Forecast Comparison )

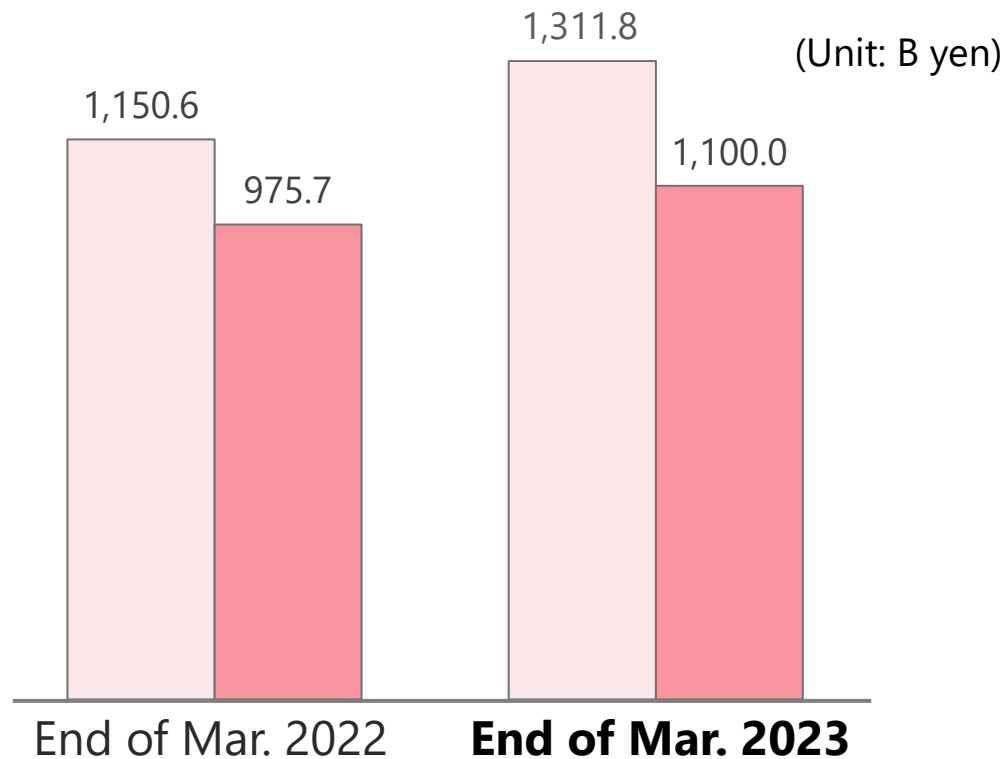


## Main Variation Factors (vs. Forecasts)

- **Royalty income (HIV franchise)**
  - Increase: Strong sales of ViiV's HIV franchise
  - ⇒ Excluding the above negative factors and the impact of exchange rates, royalty income from the HIV franchise grew 15% Y on Y
- **COVID-19 related products**
  - Decrease : Xocova sales shortfall in Asia

# Financial Position (Consolidated, IFRS)

■ Total Assets ■ Equity attributable to owners of parent



	End of Mar. 2022	End of Mar. 2023
Ratio of equity attributable to owners of parent to total assets	84.8%	83.9%

Unit: B yen		End of Mar. 2022	End of Mar. 2023	Change
Total Assets	Non-current Assets	491.4	527.6	36.2
	Current Assets	659.2	784.2	125.0
Equity attributable to owners of parent		975.7	1,100.0	124.4
Total Liabilities	Non-current Liabilities	32.9	31.4	(1.6)
	Current Liabilities	124.4	158.6	34.2

# Disposal, Acquisition and Cancellation of Treasury Stock Associated with the Establishment of the New Foundation

## Disposal of treasury stock (advantageous issuance)

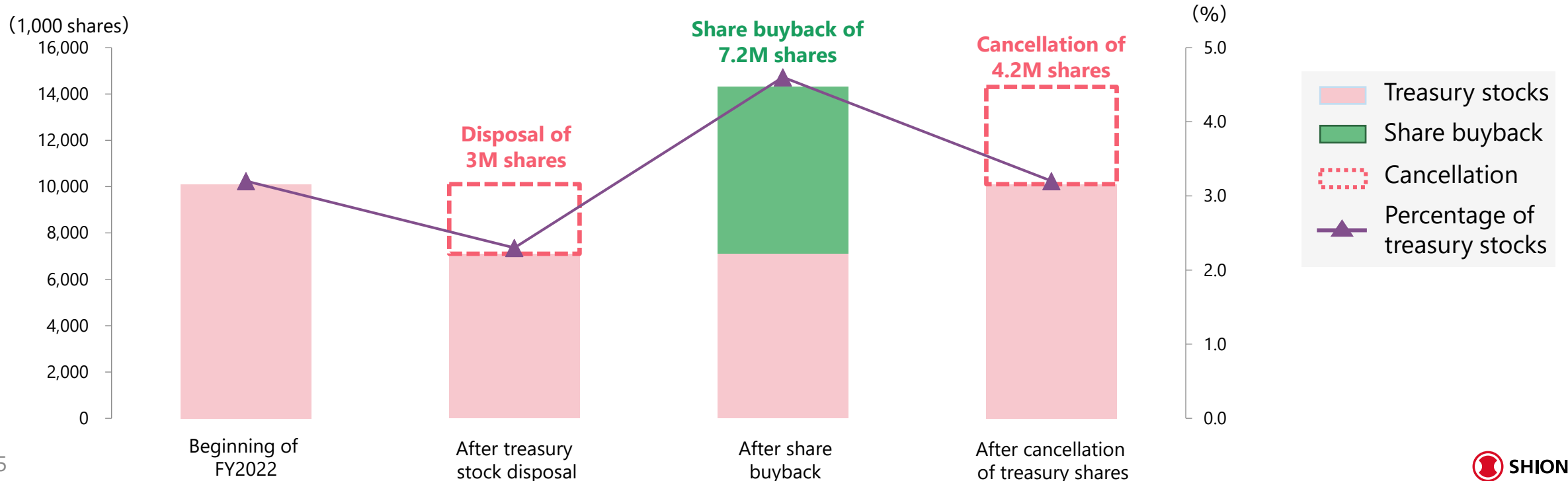
Total shares to be disposed: 3M shares  
Disposal date: September 1, 2022

## Share buyback

- Total number of shares to be acquired: 7.2M shares (maximum)
- Total purchase price for acquisition of shares: 50 billion yen (maximum)
- Period of acquisition: From June 24,2022 to December 30,2022
- **Total number of shares acquired: 7,200,000 shares (completed)**
- **Total value of shares acquired: 49,405,344,948 yen(completed)**

## Cancellation of treasury shares

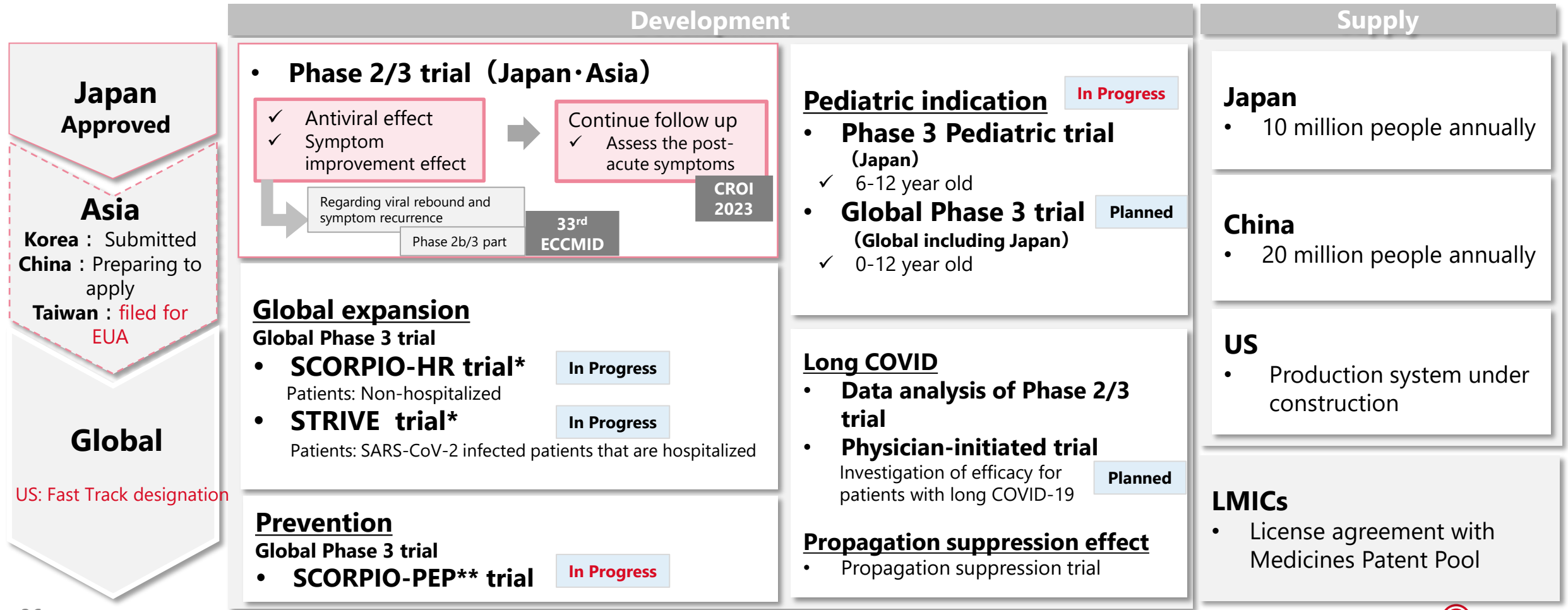
- Total shares to be cancelled: 4.2M shares
- Date for cancellation: February 10, 2023



# Xocova (Ensitrelvir): Overall Picture of the Current Situation and Future Plans

From the 3rd Quarter of Fiscal 2022 Financial Results (Partially revised)

With the emergence of new mutant strains, the need for antiviral drugs remains  
Accumulating further evidence for the role of Xocova in “with COVID” phase

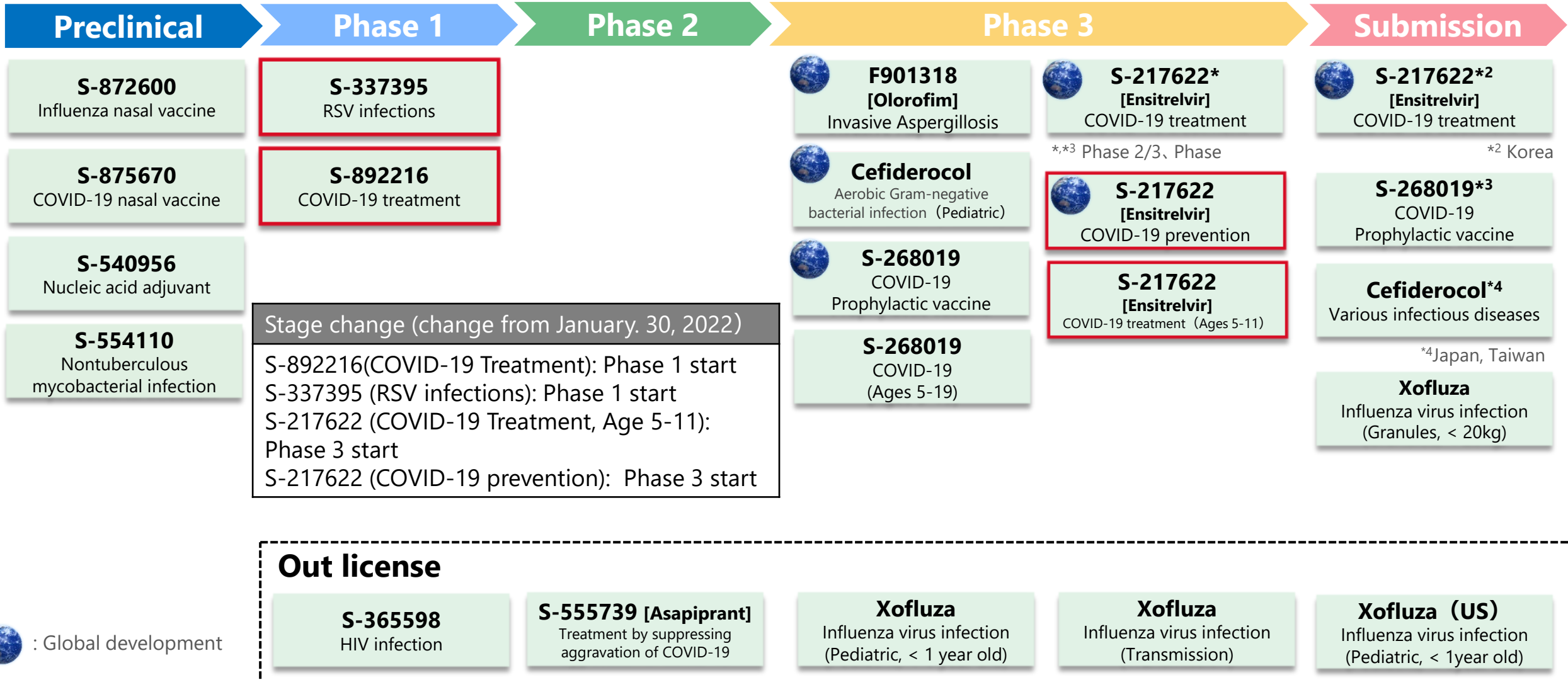


# R&D: Progress of Future Growth Driver in FY2022

Disease area	Pipeline	Origin	Indication	FY2021	FY2022
Infection	Olorofim	F2G	Invasive aspergillosis		Phase 3
	S-337395	In house	RSV infections	Preclinical	Phase 1
	S-892216	In house	COVID-19	Research	Phase 1
Psychiatry/ Nervous/Pain	Resiniferatoxin	Grünenthal	Pain associated with knee osteoarthritis		Phase 3
	S-151128	In house	Chronic pain	Preclinical	Phase 1
New growth area	S-309309	In house	Obesity	Phase 2	Phase 2
	Redasemtide	StemRIM	Dystrophic epidermolysis bullosa	Phase 2	Additional Phase 2
			Acute cerebral infarction	Phase 1	Phase 2b
Closed	S-600918	In house	Chronic with unknown cause cough	Phase 2	Closed
			Neuropathic pain	Phase 1	Closed
	S-770108	In house	Idiopathic pulmonary fibrosis	Phase 1	Closed

# Pipeline: Infectious Disease

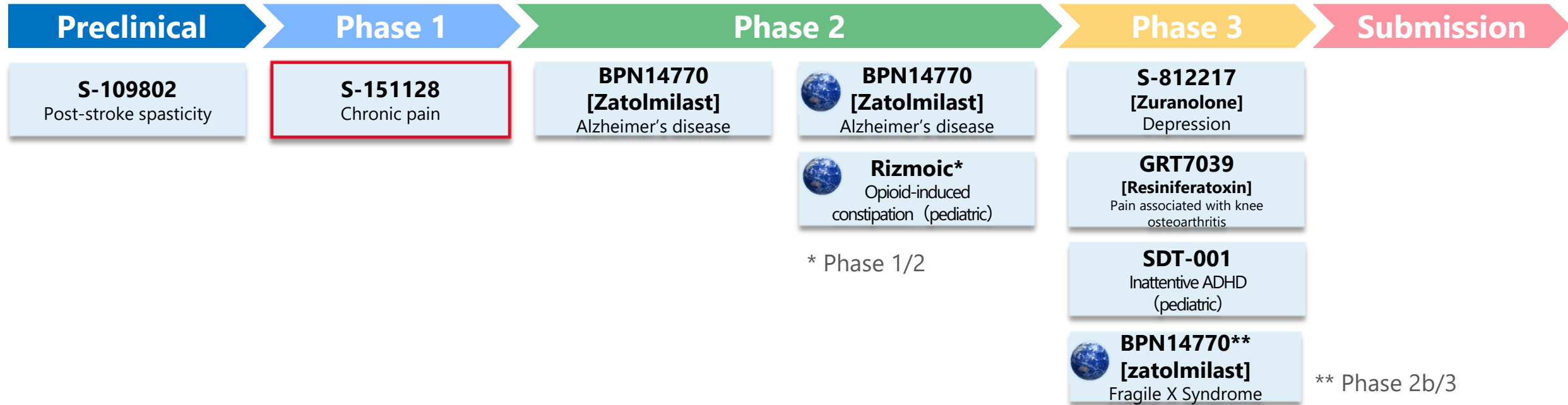
as of May 10, 2023



: Global development

# Pipeline: Psycho-Neurological Disease, Pain

as of May 10, 2023



\* Phase 1/2

\*\* Phase 2b/3

 : Global development

Stage change (change from January. 30, 2022)

S-151128 (Chronic pain): Phase 1 start  
 S-874713 (Psycho-neurological diseases) : Closed  
 S-600918 (Refractory chronic cough): Closed  
 S-600918 (Neuropathic pain): Closed

## Out license


S-0373 [Rovatrielin]  
 Spinocerebellar Degeneration


# Pipeline: New Growth Areas


as of May 10, 2023



**S-540956**  
Nucleic acid adjuvant


 **S-588210**  
Solid tumor

 **S-309309**  
Obesity

 **S-005151**  
**[Redasemtide]**  
Acute ischemic stroke

**S-588410**  
Esophageal cancer


\* Phase 1b/2

 **S-531011\***  
Solid tumor

**S-005151**  
**[Redasemtide]**  
Epidermolysis bullosa


**SR-0379**  
Cutaneous ulcer


**S-588410**  
Bladder cancer

 **S-222611**  
**[Epertinib]**  
Malignant tumor

 : Global development


**Out license**

 **S-723595**  
NASH

 **S-588410**  
Bladder cancer

**ADR-001\*\***  
Decompensated liver cirrhosis

\*\* Phase 1/2

 **S-488210**  
Head and neck squamous cell carcinoma

Stage change (change from January. 30, 2022)

S-309309(Obesity): Phase 2 start  
 S-005151(Acute ischemic stroke): Global Phase 2b start  
 S-770108(Idiopathic pulmonary fibrosis): Closed



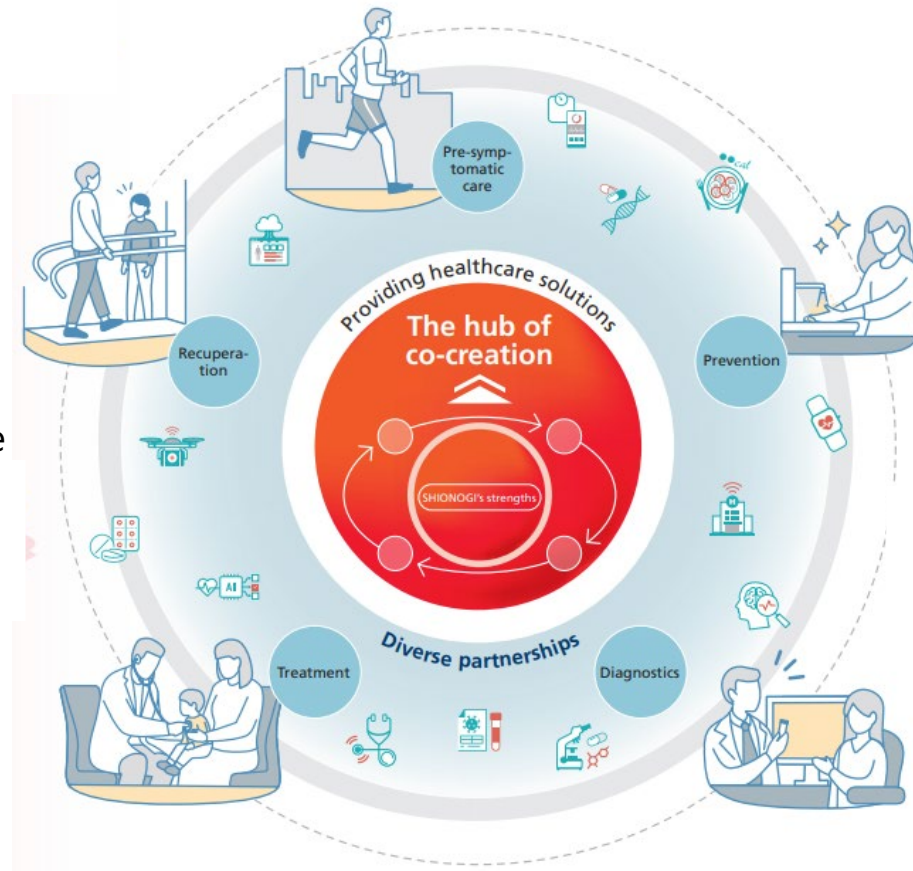
# Improved External Evaluation

	FY2018	FY2019	FY2020	FY2021	FY2022
<b>CDP</b>	Climate change : C Water Security : Non-response	Climate change : A- Water Security : A	Climate change : A- Water Security : A Supplier Engagement Leader	Climate change : A- Water Security : A- Supplier Engagement Leader	Climate change : A Water Security : A Supplier Engagement Leader
<b>FTSE</b>	Not Selected/2.9	Not Selected/2.9	Selected/3.4	Selected/3.7	Selected/3.6
<b>MSCI</b>	A	AA	AA	AA	AA
<b>DJSI</b>	Non-response/17点	Non-response/19点	Response/45 points	Response/53 points	Response/63 points The Sustainability Yearbook Member
<b>S&amp;P/JPX Carbon Efficient Index</b>	Third decline	Third decline	Fourth decline	Fifth decline	TBD
<b>SOMPO SNAM Sustainability Index</b>	Selected	Selected	Selected	Selected	Selected
<b>Survey on Health and Productivity Management</b>	Health & Productivity Stock White 500	White 500	White 500	Certified Health & Productivity Management Outstanding Organization	Certified Health & Productivity Management Outstanding Organization
<b>Integrated Report</b>	Most-Improved Integrated Reports	Most-Improved Integrated Reports	Excellent Integrated Reports	Excellent Integrated Reports	Silver Award in the WICI Second Prize in NIKKEI Award Excellent Integrated Reports

# Various Initiatives for HaaS Company

## Delivering value by providing healthcare as a service (Healthcare as a Service : HaaS\*)

- **Creation of Medical supplies**
  - Strength of SHIONOGI
- **insomnia therapeutic app**
  - commercialization agreement with SUSMED, Inc.
- **ADHD digital therapeutic app**
  - license agreement from Akili Interactive Labs, Inc.,
- **Brain wave measurement app**
  - Collaboration with PGV Inc.
- **Yui Connection establishment**
  - provides teachers with education plans appropriate for each student.



- **Vaccine business**
  - Creation of COVID-19 vaccine
  - Research and development of a nasal vaccine and a universal antigen vaccine
- **Collaboration with PxDT**
  - Efforts toward cognitive function care using gamma wave sound
- **Stream-I establishment**
  - Creation of a new information delivery model which integrates digital technology
- **Diagnostic drugs**
  - Efforts to provide diagnostic drugs for influenza and COVID-19
- **AdvanSentinel establishment**
  - Provide wastewater epidemiological surveillance service

# Other Major Progress\*

## • February

- Associate Professor Masaaki Kitajima et al. Received Committee Special Award for the theme of "Practical application of COVID-19 sewage epidemiological survey" in Japan Open Innovation Prize (JOIP)
- Forming of a Joint Venture with Accenture Co., Ltd. Accompanied by a Share Transfer of Shionogi Business Partner Co., Ltd.
- Started collaboration with Asahi Soft Drinks Co., Ltd. on educational activities for infectious disease control from 2023
- Shionogi Supports Victims of the Earthquake in Turkey and Syria
- Communication barrier-free project "Enlightenment comics for future medical workers" Crowdfunding completed

## • March

- Collaboration Agreement for the Discovery and Development of Novel Malaria Drugs with Nagasaki University and MMV, Supported by the GHIT Fund
- Concluded a partnership agreement with Kita Ward, Tokyo for "improving the ability to respond to infectious diseases at facilities for the elderly, etc."
- A Limited Partner Investment Agreement with LSP Dementia Fund

## • April

- Shionogi Certified as the First Eco-First Company in the Pharmaceutical Industry of Environmentally Advanced Company
- Conclusion of a basic agreement on support for the future of children with CEREZO OSAKA Co.,Ltd. and Any Kids Place Co., Ltd.

# Forward-Looking Statements

- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
- Materials and information provided during this presentation 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 general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials, and failure to gain market acceptance.
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