



# **FY2021 Financial Results**

## **(April 2021-March 2022)**

May 11, 2022

Shionogi & Co., Ltd.

Isao Teshirogi, President and CEO



- 1. Overview of FY2021 Financial Results (P.4-14)**
- 2. Financial Forecasts in FY2022 (P.16-20)**
- 3. Shareholder Return (P.22-23)**



# 1. Overview of FY2021 Financial Results

# Financial Results (Consolidated)



(Unit: B yen)

	Forecasts** (revised on Nov. 1)	FY2021		FY2020	Y on Y	
		Results	Achievement (%)	Results	Change (%)	Change
Revenue	294.0	<b>335.1</b>	<b>114.0</b>	297.2	<b>12.8</b>	<b>38.0</b>
Operating profit	90.0	<b>110.3</b>	<b>122.6</b>	117.4	<b>(6.1)</b>	<b>(7.1)</b>
Core operating profit*	90.0	<b>110.6</b>	<b>122.9</b>	94.0	<b>17.7</b>	<b>16.6</b>
Profit before tax	115.0	<b>126.3</b>	<b>109.8</b>	143.0	<b>(11.7)</b>	<b>(16.8)</b>
Profit attributable to owners of parent	100.0	<b>114.2</b>	<b>114.2</b>	111.9	<b>2.1</b>	<b>2.3</b>

- **Revenue and profit items are achieved revised forecasts**

- Revenue, core operating profit and profit attributable to owners of parent increased year-on-year

- **Profit items are over 100 B yen**

Exchange Rate (average)	FY2021 forecasts (revised on Nov. 1)	FY2021 results
USD (\$) – JPY (¥)	<b>110</b>	<b>112.40</b>
GBP (£) – JPY (¥)	<b>150</b>	<b>153.53</b>
EUR (€) – JPY (¥)	<b>130</b>	<b>130.56</b>

\* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

\*\* The consolidated earnings forecasts announced on Nov. 1, 2021 were written here, and the revisions to the forecasts were announced on Apr. 25, 2022

# Statement of Profit or Loss (Consolidated)



	FY2021		FY2020		Y on Y	
	Forecasts (revised on Nov. 1)	Results	Achievement (%)	Results	Change (%)	Change
Revenue	294.0	335.1	114.0	297.2	12.8	38.0
Cost of sales	19.4 57.0	16.5 55.4	97.2	17.7 52.5	5.5	2.9
Gross profit	237.0	279.7	118.0	244.7	14.3	35.1
Selling, general & administrative expenses	30.3 89.0	28.4 95.2	107.0	32.0 95.1	0.1	0.1
R&D expenses	18.9 55.5	21.8 73.0	131.5	18.3 54.2	34.6	18.7
Other income & expenses	(2.5)	(1.2)	46.7	22.1	(105.3)	(23.3)
Operating profit	30.6 90.0	32.9 110.3	122.6	39.5 117.4	(6.1)	(7.1)
Core operating profit*	30.6 90.0	33.0 110.6	122.9	31.6 94.0	17.7	16.6
Finance income & costs	25.0	16.0	63.8	25.6	(37.6)	(9.6)
Profit before tax	39.1 115.0	37.7 126.3	109.8	48.1 143.0	(11.7)	(16.8)
Profit attributable to owners of parent	100.0	114.2	114.2	111.9	2.1	2.3

(Unit: B yen)

## Main Variation Factors ( Forecast Comparison\*\*\*)

- **Revenue**
  - Increase: Royalty income (HIV franchise)
  - Decrease: Prescription drugs
- **Selling, general & administrative expenses**
  - Increase: Launch and sales activity costs associated with strong sales of Fetroja® and Fetrocroja®, launch preparation cost for S-217622
- **R&D**
  - Increase: Concentrated investment in R&D activities related to COVID-19
- **Finance income & costs**
  - Decrease in income :Shift to FY2022 in receiving dividend from ViiV in the 4th quarter of FY2021

# Revenue by Segment



	FY2021		FY2020		Y on Y	
	Forecasts (revised on Nov. 1) <sup>**</sup>	Results	Achievement (%)	Results	Change (%)	Change
<b>Prescription drugs</b>	94.4	<b>89.1</b>	<b>94.4</b>	94.7	<b>(5.9)</b>	<b>(5.6)</b>
<b>Overseas subsidiaries/export</b>	35.0	<b>34.4</b>	<b>98.3</b>	24.6	<b>39.5</b>	<b>9.7</b>
<b>Shionogi Inc.</b>	12.7	<b>13.8</b>	<b>108.5</b>	7.5	<b>84.5</b>	<b>6.3</b>
Fetroja®	-	<b>6.2</b>	-	1.7	<b>268.7</b>	<b>4.6</b>
<b>Ping An-Shionogi* /C&amp;O</b>	12.3	<b>10.2</b>	<b>82.6</b>	10.1	<b>1.1</b>	<b>0.1</b>
<b>SBV(Europe)</b>	5.0	<b>5.0</b>	<b>99.8</b>	2.0	<b>153.7</b>	<b>3.0</b>
<b>Contract manufacturing</b>	17.8	<b>17.4</b>	<b>97.9</b>	19.7	<b>(11.7)</b>	<b>(2.3)</b>
<b>OTC and quasi-drug</b>	13.4	<b>11.2</b>	<b>83.0</b>	11.7	<b>(4.8)</b>	<b>(0.6)</b>
<b>Royalty income</b>	132.0	<b>181.3</b>	<b>137.4</b>	144.6	<b>25.3</b>	<b>36.6</b>
<b>HIV franchise</b>	125.2	<b>174.0</b>	<b>138.9</b>	123.4	<b>41.0</b>	<b>50.6</b>
Crestor®	-	<b>1.2</b>	-	16.6	<b>(93.1)</b>	<b>(15.4)</b>
<b>Others</b>	6.7	<b>6.1</b>	<b>91.5</b>	4.7	<b>30.8</b>	<b>1.4</b>
<b>Others</b>	1.4	<b>1.8</b>	<b>124.4</b>	1.8	<b>1.7</b>	<b>0.0</b>
<b>Total</b>	294.0	<b>335.1</b>	<b>114.0</b>	297.2	<b>12.8</b>	<b>38.0</b>

(Unit: B yen)

## Main Variation Factors ( Forecast Comparison<sup>\*\*\*</sup>)

- **Prescription drugs**
  - Decrease: Sales of Influenza franchise
- **Overseas subsidiaries/export**
  - US: Increase: Sales of cefiderocol (Fetroja®)
  - China: Decrease: Sales on online medical platform
- **OTC and quasi-drug**
  - Decrease: sales of ISODINE®
- **Royalty income**
  - HIV franchise
    - : Increase: Royalty income from the conclusion of dolutegravir patent license agreement (transient factor)
    - HIV royalties excluding the one-time payment increased year-on-year

# Revenue from Prescription Drugs in Japan



(Unit: B yen)

	FY2021		FY2020	Y on Y	
	Forecasts* (revised on Nov. 1)	Results	Results	Change (%)	Change
<b>Cymbalta®</b>	17.1	<b>15.9</b>	26.5	<b>(39.9)</b>	<b>(10.6)</b>
<b>Intuniv®</b>	16.6	<b>16.4</b>	13.1	<b>25.4</b>	<b>3.3</b>
<b>Vyvanse®</b>	1.0	<b>0.8</b>	0.3	<b>190.7</b>	<b>0.5</b>
<b>Infectious disease drugs</b>	16.6	<b>11.8</b>	9.8	<b>20.8</b>	<b>2.0</b>
Influenza franchise	7.9	<b>3.1</b>	0.3	-	<b>2.8</b>
<b>OxyContin® franchise</b>	5.0	<b>4.8</b>	5.3	<b>(10.0)</b>	<b>(0.5)</b>
<b>Symproic®</b>	3.1	<b>2.7</b>	2.3	<b>17.9</b>	<b>0.4</b>
<b>Actair®</b>	0.4	<b>0.5</b>	0.3	<b>45.1</b>	<b>0.2</b>
<b>Mulpleta®</b>	0.1	<b>0.1</b>	0.1	<b>8.9</b>	<b>0.0</b>
<b>Pirespa®</b>	3.5	<b>3.8</b>	5.1	<b>(25.3)</b>	<b>(1.3)</b>
<b>Others</b>	30.8	<b>32.4</b>	32.0	<b>1.2</b>	<b>0.4</b>
Crestor®	5.7	<b>5.9</b>	6.7	<b>(11.0)</b>	<b>(0.7)</b>
Irbetan® franchise	3.1	<b>3.2</b>	3.3	<b>(5.0)</b>	<b>(0.2)</b>
<b>Prescription drugs</b>	<b>94.4</b>	<b>89.1</b>	<b>94.7</b>	<b>(5.9)</b>	<b>(5.6)</b>

<Products included in infectious disease drugs>

- |                     |             |              |            |
|---------------------|-------------|--------------|------------|
| • Xofluza®          | • FINIBAX®  | • Shiomarin® | • Flagyl®  |
| • Rapiacta®         | • Flumarin® | • Vancomycin | • ISODINE® |
| • Brightpoc®Flu•Neo | • Flomox®   | • Baktar®    |            |

# Summary of FY2021 Results



- **Domestic business**
  - Domestic prescription drugs have not achieved the forecast due to a very small epidemic of influenza
  - OTC and quasi-drug has not achieved the forecast due to sales of ISODINE® while new products are steadily progressing
- **Overseas business**
  - Sales of cefiderocol in the United States and Europe are steadily progressing
- **Selling, general & administrative expenses**
  - Launch and sales activity costs associated with strong sales of Fetroja® and Fetcroja®
- **R&D expenses**
  - Due to Concentrated investment in R&D activities related to COVID-19, 73 billion yen (up 18.7-billion-yen year-on-year comparison) which is the largest amount ever
- **Settlement of dolutegravir patent infringement litigation with Gilead**
  - Recognized royalty on upfront and on an agreed projection of future royalty payments as revenue by the conclusion of the patent license agreement

**Achieved Initial and revised forecasts**



# Actions for the Early Termination of COVID-19



## Epidemic forecasting



Launch of sewage epidemiology surveillance survey service

## Prevention



Development of **S-268019**

## Diagnosis



Th2 chemokine TARC\*  
kit, antigen-test kit

## Treatment



Development of **S-217622**

## Exacerbation suppression



Development of Asapiprant

**Established AdvanSentinel**  
Early detection of BA.2  
(Refer to next page)

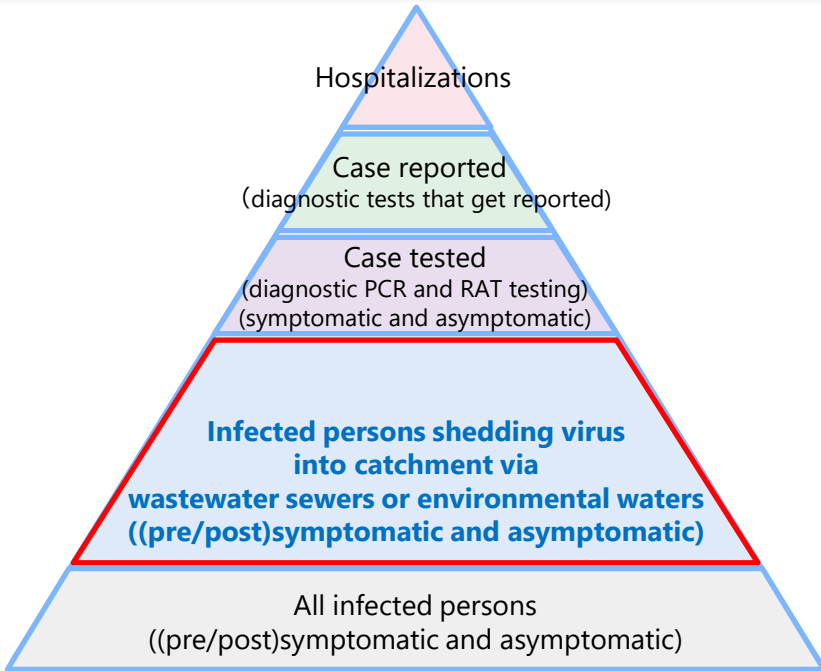
**Verification of non-inferiority with COMIRNATY intramuscular injection (Pfizer) in additional immunological test**

**Joint sale of antigen-test kit using saliva specimen**

**Completion of domestic approval application with the result of Phase 2a/2b**

**Ph2 trial started**

**Although S-217622 and S-268019 were not put into practical use by FY2021, each action was greatly advanced at a speed that breaks the established concept**



※ WHO : Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance\*<sup>1</sup>

## AdvanSentinel

- **Early social implementation of wastewater monitoring**
  - Partnering with SHIMADZU
  - **Wastewater monitoring is an indispensable method to grasp more accurate infectious status of society as a whole, because of in terms of less affected way for unique bias that clinical tests such as PCR or RAT test always have**
  - **US and Europe were progress social implementation during COVID-19 pandemic**
    - > US: CDC has been leading wastewater monitoring in 46 states and published the results on dashboard with clinical tests\*<sup>2</sup>
    - > Europe: All EU Member States have agreed with the European Commission recommendation and around 1370 wastewater treatment plants are under regular surveillance and share the data with each countries\*<sup>3</sup>
- **Actions for FY2022**
  - **Dissemination of wastewater epidemiological surveys and evidence building activities through supplementary budget and Ministry of Land, Infrastructure, Transport and Tourism projects**
  - **launch of the kit of new method that can be super high-sensitive and automated**

**Building a new method that is super high-sensitive and automated, we will contribute to grasp more accurate infectious status worldwide**

<sup>1</sup> Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance (who.int)

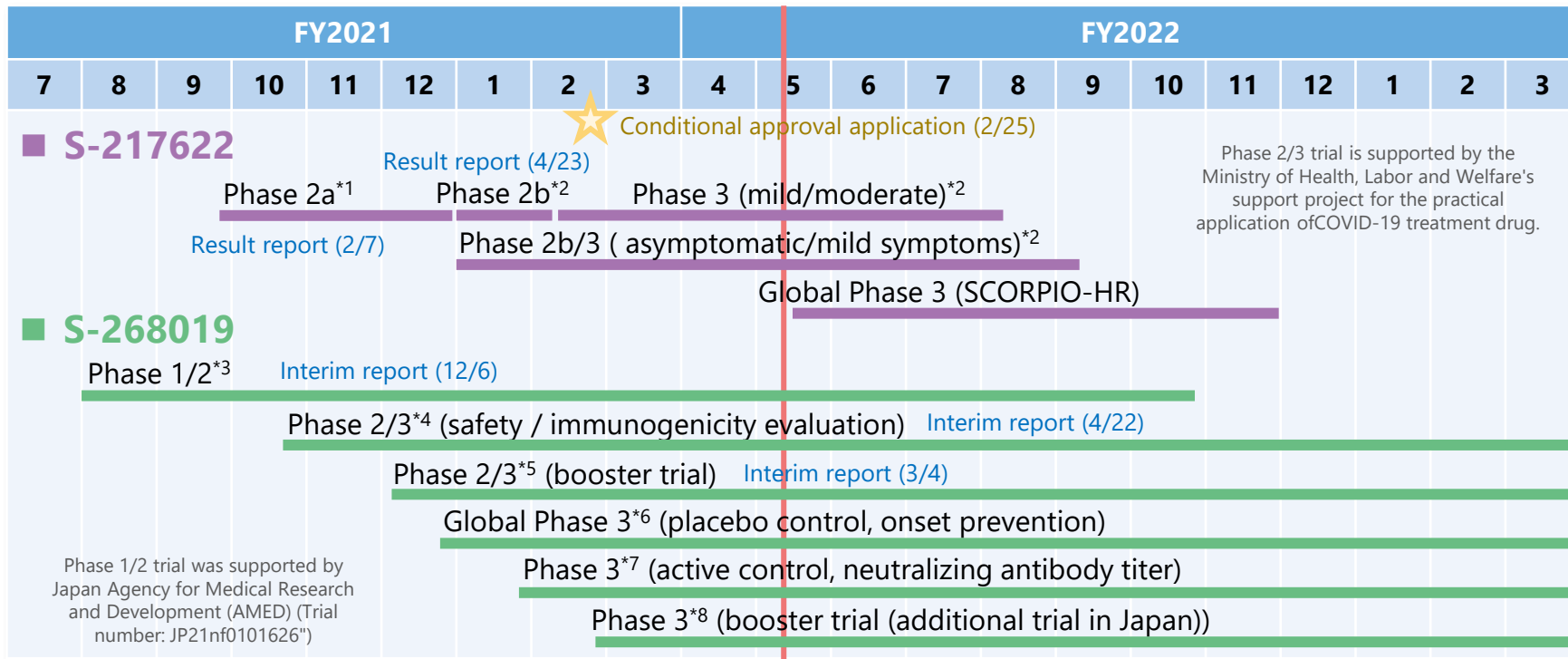
<sup>2</sup> National Wastewater Surveillance System (NWSS) – a new public health tool to understand COVID-19 spread in a community | CDC

<sup>3</sup> Coronavirus response: monitoring of wastewater contributes to tracking coronavirus and variants across all EU countries (europa.eu)

# Progress Summary of S-217622, S-268019



As of May 11, 2022



Phase 1/2 trial was supported by Japan Agency for Medical Research and Development (AMED) (Trial number: JP21nf0101626")

\*1 [jRCT2031210202](#), \*2 [jRCT2031210350](#), \*3 [jRCT2031210269](#), \*4 [jRCT2031210383](#), \*5 [jRCT2031210470](#), \*6 [NCT05212948](#), \*7 [jRCT2051210151](#), \*8 [jRCT2031210613](#)



## S-217622 (oral therapeutic drug)

- **Domestic manufacturing and marketing approval application**
  - Application based on the analysis results of the evaluation items of Phase 2b part (February 25, 2022)
- **Phase 2b result report**
  - Efficacy and safety results announced at 32<sup>nd</sup> ECCMID\*
- **Continuation of Phase 2/3 trial**
  - Phase 3 part (mild/moderate) and Phase 2b/3 part (asymptomatic/mild symptoms) are underway
    - > Patient registration is proceeding smoothly including Vietnam and South Korea
- **Global Phase 3 trial started**
  - Preparing to Initiate ACTIV-2d (SCORPIO-HR trial) in collaboration with ACTG\*\*
- **Supply**
  - Completed production for 1 million people
  - Since April 2022, production is expanding to supply more than 10 million people annually
  - Started preparations for building a global supply system

**Each action is progressing for domestic and global provision**



## S-268019 (recombinant protein vaccine)

### 5 Pivotal clinical trials in progress

- **Phase 2/3 trial**
  - Safety/immunogenicity evaluation trial in 3,100 adults aged 20 and over and the elderly aged 65 and over
  - Top-Line results: Disclosed at the Infectious Diseases Society (April 22, 2022)
- **Active control, neutralizing antibody titer trial**
  - Superiority verification trial over VAXZEVRIA (AstraZeneca)
  - Top-Line results will be obtained in May (scheduled to be published in a paper)
- **Phase 2/3 booster trial**
  - Non-inferiority verification trial with COMIRNATY (Pfizer) by booster immunization after 2 doses of COMIRNATY
  - Achieved the primary endpoint in the interim report
- **Phase 3 booster trial (additional trial in Japan)**
  - For adults aged 20 to 64 years who received twice SPIKEVAX (Moderna) and elderly people aged 65 years or older who received twice COMIRNATY or SPIKEVAX
  - Top-Line results will be obtained in May
- **Placebo control, onset prevention trial**
  - Advance start in Vietnam from December 2021
  - Subject registration is progressing smoothly

**Each trial is steadily progressing toward the acquisition of both initial immunity and booster immunity indications**

# Results for FY2021 and Issues Left Behind



## Results for FY2021

**Achieved forecasts**

**Progress of  
COVID-19 related  
projects**

**Sophistication  
and speed of  
decision making**

## Issues left behind

**Early commercialization of  
COVID-19 therapeutic and  
vaccines**

**Development of  
growth drivers**

**Strengthening  
domestic/overseas  
business**

**Focus on efforts for medium- to long-term growth in parallel  
with aiming to provide solutions for COVID-19 early**

## **2. Actions and Financial Forecasts in FY2022**

# Financial Forecasts (Consolidated)



(Unit: B yen)

	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	400.0	180.0	335.1	19.4	64.9
Operating profit	120.0	57.0	110.3	8.8	9.7
Core operating profit*	120.0	57.0	110.6	8.5	9.4
Profit before tax	168.0	86.0	126.3	33.0	41.7
Profit attributable to owners of parent	136.0	71.5	114.2	19.1	21.8

**A year to connect the profits from COVID-19 related projects to the next growth**

Exchange Rate (average)	FY2022 Forecasts	FY2021 Results
USD (\$) – JPY (¥)	125	112.40
GBP (£) – JPY (¥)	160	153.53
EUR (€) – JPY (¥)	135	130.56



# Statement of Profit or Loss Forecast (Consolidated)



	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	<b>400.0</b>	<b>180.0</b>	335.1	<b>19.4</b>	<b>64.9</b>
Cost of Sales	<b>22.0</b>	<b>17.5</b>	16.5		
	<b>88.0</b>	<b>31.5</b>	55.4	<b>58.8</b>	<b>32.6</b>
Gross profit	<b>312.0</b>	<b>148.5</b>	279.7	<b>11.5</b>	<b>32.3</b>
Selling, general& administrative expenses	<b>30.0</b>	<b>32.8</b>	28.4		
	<b>120.0</b>	<b>59.0</b>	95.2	<b>26.0</b>	<b>24.8</b>
R&D expenses	<b>17.5</b>	<b>17.8</b>	21.8		
	<b>70.0</b>	<b>32.0</b>	73.0	<b>(4.1)</b>	<b>(3.0)</b>
Other income & expenses	<b>(2.0)</b>	<b>(0.5)</b>	(1.2)	<b>71.5</b>	<b>(0.8)</b>
Operating profit*	<b>30.0</b>	<b>31.7</b>	32.9		
	<b>120.0</b>	<b>57.0</b>	110.3	<b>8.8</b>	<b>9.7</b>
Core operating profit	<b>30.0</b>	<b>31.7</b>	33.0		
	<b>120.0</b>	<b>57.0</b>	110.6	<b>8.5</b>	<b>9.4</b>
Finance income & costs	<b>48.0</b>	<b>29.0</b>	16.0	<b>200.8</b>	<b>32.0</b>
Profit before tax	<b>42.0</b>	<b>47.8</b>	37.7		
	<b>168.0</b>	<b>86.0</b>	126.3	<b>33.0</b>	<b>41.7</b>
Profit attributable to owners of parent	<b>136.0</b>	<b>71.5</b>	114.2	<b>19.1</b>	<b>21.8</b>

(Unit: B yen)

# Revenue Forecast by Segment



	FY2022 Forecasts		FY2021	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Prescription drugs	<b>78.6</b>	<b>35.5</b>	89.1	<b>(11.8)</b>	<b>(10.5)</b>
Overseas subsidiaries/export	<b>41.6</b>	<b>18.1</b>	34.4	<b>21.2</b>	<b>7.3</b>
Shionogi Inc.	<b>13.0</b>	<b>6.0</b>	13.8	<b>(6.0)</b>	<b>(0.8)</b>
Ping An-Shionogi* /C&O	<b>14.8</b>	<b>6.3</b>	10.2	<b>45.1</b>	<b>4.6</b>
SBV(Europe)	<b>8.4</b>	<b>3.4</b>	5.0	<b>67.9</b>	<b>3.4</b>
Contract manufacturing	<b>14.8</b>	<b>6.3</b>	17.4	<b>(15.3)</b>	<b>(2.7)</b>
OTC and quasi-drug	<b>13.4</b>	<b>6.3</b>	11.2	<b>20.0</b>	<b>2.2</b>
Royalty income	<b>140.4</b>	<b>68.2</b>	181.3	<b>(22.5)</b>	<b>(40.9)</b>
HIV franchise	<b>133.9</b>	<b>67.0</b>	174.0	<b>(23.0)</b>	<b>(40.1)</b>
Crestor®	-	-	1.2	-	<b>(1.2)</b>
Others	<b>6.5</b>	<b>1.2</b>	6.1	<b>5.9</b>	<b>0.4</b>
COVID-19 related products**	<b>110.0</b>	<b>45.0</b>	-	-	-
Others	<b>1.2</b>	<b>0.6</b>	1.8	<b>(65.3)</b>	<b>(0.6)</b>
<b>Total</b>	<b>400.0</b>	<b>180.0</b>	335.1	<b>19.4</b>	<b>64.9</b>

(Unit: B yen)

# Medium- to Long-term Commitment as a Leading Company in Infectious Diseases



**Materiality that Shionogi should tackle: “Protect people worldwide from the threat of infectious diseases”**

## Participate in industry activities and R&D funds

- Provision of R&D investment and technical support through participation in AMR\* Action Fund, GHIT Fund, etc.
- Dialogue with national governments to develop sound markets
- Lobbying for establishment of clinical trial networks and deregulation on a global basis

## Continue drug discovery research by making use of our strengths

- Initiatives in serious infectious diseases incl. viral infectious diseases, the three major infectious diseases and AMR
- Initiatives in Neglected Tropical Diseases (NTDs) that are overlooked
- Expansion into total care against infectious diseases

## Collaborate to generate innovation and maximize product value

- Collaboration with academia, ventures and other industries that strive to tackle infectious diseases
- Collaborations in overseas development and marketing
- Partnering for expansion of LMICs access

**Continuous production, support and development of researchers and research institutions are essential for sustaining innovation that can meet unmet needs related to infectious diseases and prepare against unknown threats**

**Establish Shionogi’s own, new foundation that supports and encourages research in Japan**

# Establishment of SHIONOGI INFECTIOUS DISEASE RESEARCH PROMOTION FOUNDATION



- **Background of the establishment**
  - Society & Economy: The importance of infectious disease research was reaffirmed due to the once-in-a-lifetime COVID-19 pandemic
  - Pharmaceutical companies: Efforts against infectious diseases have tended to be reduced or withdrawn from a business feasibility perspective, leading to loss of employment opportunities for researchers
  - Academia: Lack of funds and employments irrespective of the disease area and the avoidance of infectious disease area where the market size is small have posed a problem for the fostering of young researchers  
⇒ **Considering a new academia research support scheme**
- **Activity details (Annual budget: Around 300 million yen is planned)**
  - Granting subsidies for research on infectious diseases; awarding distinguished achievements
  - Hosting lectures and symposiums on infectious diseases ..and more
- **Interest bearing issuance of treasury shares with Sumitomo Mitsui Trust Bank as the trustee and the Foundation as the beneficiary (3 million shares)**
  - To be submitted as a matter for special resolution at the 157th Annual General Meeting of Shareholders to be held on June 23, 2022

**Fulfill our corporate social responsibilities  
by supporting and encouraging research in the infectious disease area,  
thereby contributing to academic promotion and the welfare of mankind**

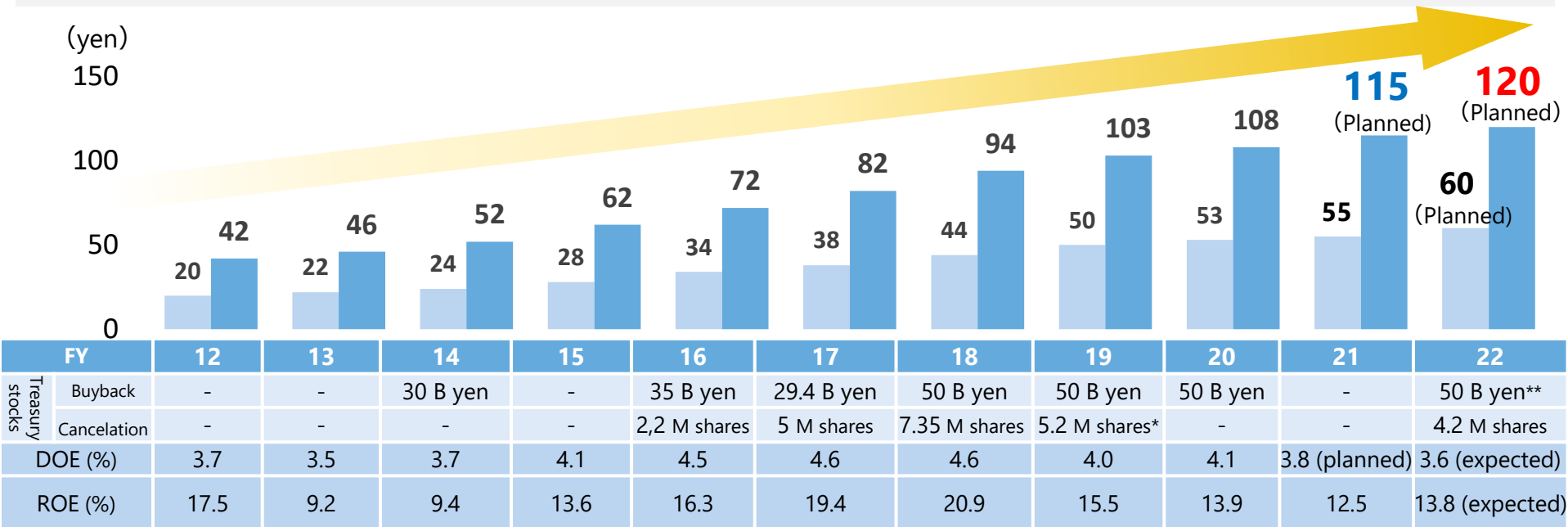
# 3. Shareholder return

# 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
- **Plan to increase dividend again for the 11th consecutive year** in FY2022



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



## Disposal of treasury stock (advantageous issuance)

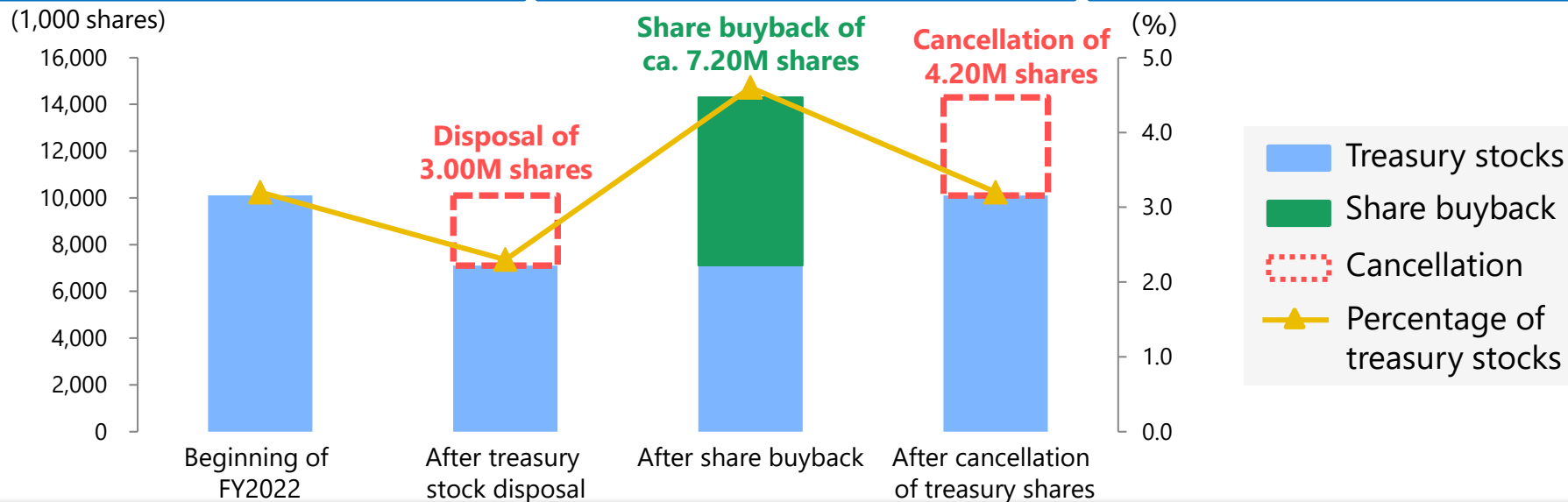
- Total shares to be disposed : 3.00M
- Disposal date: Scheduled to be Decided by the Board of Directors after the general meeting of shareholders scheduled to be held on June 23, 2022

## Share buyback

- Share buyback: 7.20M shares (upper limit)
- Total amount of buyback: 50 B yen (upper limit)
- Period: After the general meeting of shareholders scheduled to be held on June 23, 2022 ~ 2022/12/31

## Cancellation of treasury shares

- Total shares to be cancelled: 4.20M shares
- Date for cancellation: Feb,10, 2023



# Appendix



# Pipeline: Infectious Disease



as of May. 11, 2022



<b>S-872600</b> Influenza nasal vaccine	<b>S-880008</b> COVID-19 treatment (peptide)	<b>S-217622</b> COVID-19 treatment	<b>S-217622*</b> COVID-19 treatment <span>Up</span>
<b>S-875670</b> <span>Up</span> COVID-19 nasal vaccine	<b>S-540956</b> Nucleic acid adjuvant	<b>S-268019</b> COVID-19 Prophylactic vaccine	* Phase 2/3
<b>S-554110</b> <span>Up</span> Nontuberculous mycobacterial infection	<b>S-337395</b> <span>Up</span> RSV infectious	<b>S-268019</b> COVID-19 Prophylactic vaccine	<b>cefiderocol</b> <span>Up</span> Various infectious diseases
		<b>cefiderocol</b> Aerobic Gram-negative bacterial infection (Pediatric)	<b>Xofluza®</b> Influenza virus infection (Granules, < 20 kg)

: Global development

## Out license

<b>S-365598</b> HIV infection	<b>S-555739</b> Treatment by suppressing aggravation of COVID-19	<b>Xofluza®</b> Influenza virus infection (Pediatric, < 1 year old)	<b>Xofluza® (US)</b> Influenza virus infection (Pediatric, over 1 year old)
		<b>Xofluza®</b> Influenza virus infection (Transmission)	

Stage change (Changes from Jan. 31, 2022)

S-217622 (COVID-19 treatment) : Submission (Japan)  
 cefiderocol (Various infectious diseases) : Submission (Japan)  
 S-875670 (COVID-19 nasal vaccine)  
 S-554110 (Nontuberculous mycobacterial infection)  
 S-337395 (RSV infectious)

# Pipeline: Psycho-neurological Disease



as of May. 11, 2022



Preclinical	Phase 1	Phase 2	Phase 3	Submission
<b>S-874713</b> Psycho-neurological diseases	<b>S-600918 [sivopixant]</b> Neuropathic pain	<b>S-600918 [sivopixant]</b> Refractory chronic cough	<b>S-600918 [sivopixant]</b> Refractory chronic cough	<b>S-812217 [zuranolone]</b> Depression
<b>S-109802</b> Post-stroke spasticity	<b>S-010887</b> Neuropathic pain	<b>BPN14770 [zatolmilast]</b> Alzheimer's disease	<b>BPN14770 [zatolmilast]</b> Alzheimer's disease	<b>BPN14770** [zatolmilast]</b> Fragile X Syndrome <span style="color:red">Up</span>
	<b>S-120083</b> Inflammatory pain		<b>Rizmoic®*</b> Opioid-induced constipation(pediatric) * Phase 1/2	<b>SDT-001</b> Inattentive ADHD (pediatric) <span style="color:red">Up</span>
	<b>S-117957</b> Insomnia		<b>S-120083</b> Inflammatory pain	

**Out license**

- S-0373[rovatirelin]**  
Spinocerebellar Degeneration

: Global development

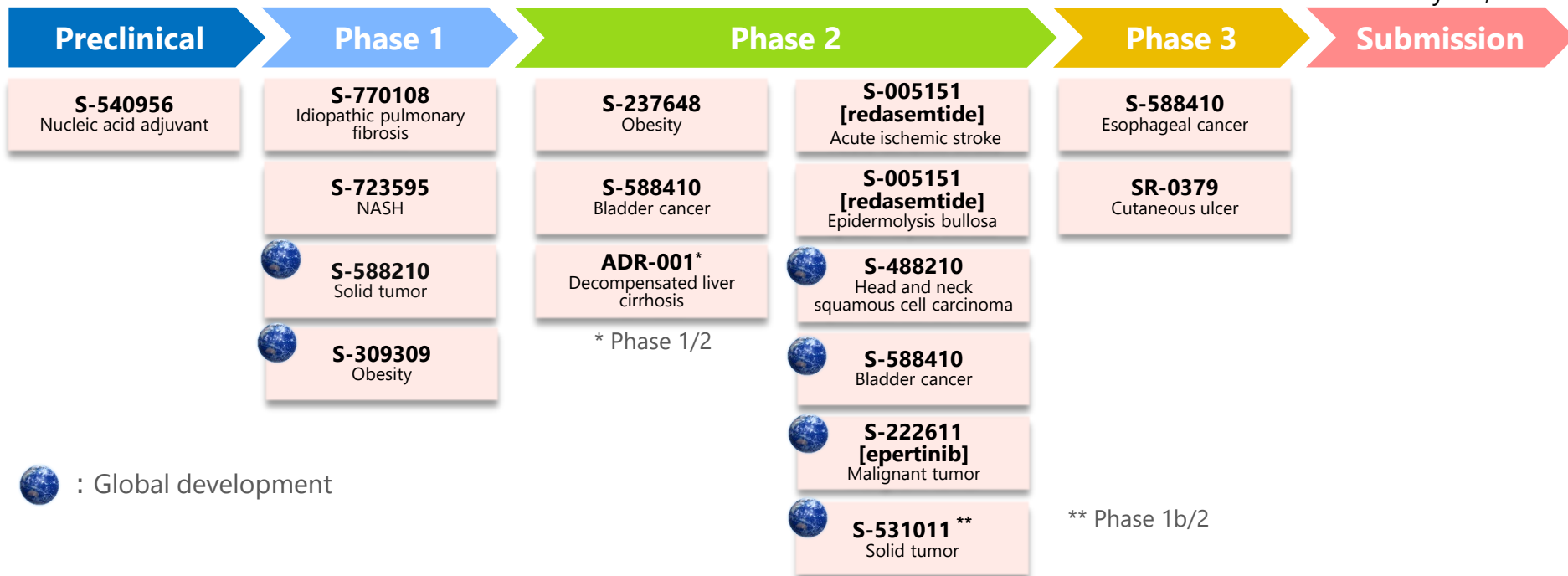
Stage change (Changes from Jan. 31, 2022)

- BPN14770 (Fragile X Syndrome) : Phase 2b/3 start
- SDT-001 : Phase3 start
- S-637880 (Neuropathic low back pain) : Closed

# Pipeline: New Growth Areas



as of May. 11, 2022



: Global development

# Revenue Forecasts for Prescription Drugs in Japan



(Unit: B yen)

	FY2022 Forecasts		FY2021	Y on Y	
	Forecasts	1H	Results	Change (%)	Change (B yen)
Intuniv®	19.5	9.0	16.4	19.1	3.1
Vyvanse®	1.1	0.5	0.8	38.9	0.3
Infectious disease drugs	13.4	4.3	11.8	13.6	1.6
Influenza franchise	5.1	0.3	3.1	66.5	2.0
Cymbalta®	6.1	3.1	15.9	(61.7)	(9.8)
OxyContin® franchise	4.5	2.3	4.8	(6.5)	(0.3)
Symproic®	3.3	1.5	2.7	24.1	0.6
Actair®	0.6	0.3	0.5	16.4	0.1
Mulpleta®	0.1	0.1	0.1	2.4	0.0
Pirespa®	2.4	1.2	3.8	(37.8)	(1.4)
Others	27.6	13.3	32.4	(14.6)	(4.7)
Crestor®	3.3	1.7	5.9	(43.6)	(2.6)
Irbetan® franchise	2.6	1.2	3.2	(18.8)	(0.6)
<b>Prescription drugs</b>	<b>78.6</b>	<b>35.5</b>	<b>89.1</b>	<b>(11.8)</b>	<b>(10.5)</b>

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc®Flu・Neo

- FINIBAX®
- Flumarin®
- Flomox®

- Shiomarin®
- Vancomycin
- Baktar®

- Flagyl®
- ISODINE®

# Revenue from Prescription Drugs in Japan



	Forecasts* (revised on Nov. 1)	FY2021		FY2020	Y on Y	
		Results	Achievement (%)	Results	Change (%)	Change
Cymbalta®	17.1	15.9	92.9	26.5	(39.9)	(10.6)
Intuniv®	16.6	16.4	98.5	13.1	25.4	3.3
Vyvanse®	1.0	0.8	74.9	0.3	190.7	0.5
<b>Infectious disease drugs</b>	16.6	11.8	70.9	9.8	20.8	2.0
Influenza franchise	7.9	3.1	39.0	0.3	-	2.8
OxyContin® franchise	5.0	4.8	95.9	5.3	(10.0)	(0.5)
Symproic®	3.1	2.7	85.8	2.3	17.9	0.4
Actair®	0.4	0.5	129.4	0.3	45.1	0.2
Mulpleta®	0.1	0.1	92.0	0.1	8.9	0.0
Pirespa®	3.5	3.8	109.6	5.1	(25.3)	(1.3)
<b>Others</b>	30.8	32.4	104.9	32.0	1.2	0.4
Crestor®	5.7	5.9	104.2	6.7	(11.0)	(0.7)
Irbetan® franchise	3.1	3.2	103.0	3.3	(5.0)	(0.2)
<b>Prescription drugs</b>	94.4	89.1	94.4	94.7	(5.9)	(5.6)

(Unit: B yen)

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu・Neo

- FINIBAX®
- Flumarin®
- Flomox®

- Shiomarin®
- Vancomycin
- Baktar®

- Flagyl®
- ISODINE®

# Statement of Profit or Loss (Consolidated)



	FY2021			FY2020		Y on Y	
	Forecasts** (revised on Nov. 1)	Results	Achievement (%)	Results	Change (%)	Change	
Revenue	294.0	335.1	114.0	297.2	12.8	38.0	
Cost of sales	19.4 57.0	16.5 55.4	97.2	17.7 52.5	5.5	2.9	
Gross profit	237.0	279.7	118.0	244.7	14.3	35.1	
Selling, general & administrative expenses	30.3 89.0	28.4 95.2	107.0	32.0 95.1	0.1	0.1	
R&D expenses	18.9 55.5	21.8 73.0	131.5	18.3 54.2	34.6	18.7	
Other income & expenses	(2.5)	(1.2)	46.7	22.1	(105.3)	(23.3)	
Operating profit	30.6 90.0	32.9 110.3	122.6	39.5 117.4	(6.1)	(7.1)	
Core operating profit*	30.6 90.0	33.0 110.6	122.9	31.6 94.0	17.7	16.6	
Finance income & costs	25.0	16.0	63.8	25.6	(37.6)	(9.6)	
Profit before tax	39.1 115.0	37.7 126.3	109.8	48.1 143.0	(11.7)	(16.8)	
Profit attributable to owners of parent	100.0	114.2	114.2	111.9	2.1	2.3	

(Unit: B yen)

## Main Variation Factors (Year-on-Year Comparison)

- **Revenue**
  - Increase: Overseas subsidiaries/export : Royalty income (HIV franchise)
  - Decrease: Prescription drugs (Cymbalta®)
- **Cost of sales**
  - Increase: Product mix due to growth in overseas subsidiaries/export, contract manufacturing
- **R&D expenses**
  - Increase: Concentrated investment in R&D activities related to COVID-19
- **Other income & expenses**
  - Decrease in income: Recognized a gain on the exchange of the Shionogi Shibuya Building in 3Q of the previous year (22.9 B yen)
- **Finance income & costs**
  - Decrease in income: Shift to FY2022 in receiving dividend from ViiV in the 4th quarter of FY2021
- **Profit attributable to owners of parent**
  - Increase: Received a refund regarding a favorable Judgement on the complaint for the rescission of tax reassessment by Osaka Regional Taxation Bureau

# Revenue by Segment



(Unit: B yen)

	FY2021		FY2020		Y on Y	
	Forecasts (revised on Nov. 1)	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	94.4	89.1	94.4	94.7	(5.9)	(5.6)
Overseas subsidiaries/export	35.0	34.4	98.3	24.6	39.5	9.7
Shionogi Inc.	12.7	13.8	108.5	7.5	84.5	6.3
Fetroja®	-	6.2	-	1.7	268.7	4.6
Ping An-Shionogi* /C&O	12.3	10.2	82.6	10.1	1.1	0.1
SBV(Europe)	5.0	5.0	99.8	2.0	153.7	3.0
Contract manufacturing	17.8	17.4	97.9	19.7	(11.7)	(2.3)
OTC and quasi-drug	13.4	11.2	83.0	11.7	(4.8)	(0.6)
Royalty income	132.0	181.3	137.4	144.6	25.3	36.6
HIV franchise	125.2	174.0	138.9	123.4	41.0	50.6
Crestor®	-	1.2	-	16.6	(93.1)	(15.4)
Others	6.7	6.1	91.5	4.7	30.8	1.4
Others	1.4	1.8	124.4	1.8	1.7	0.0
<b>Total</b>	<b>294.0</b>	<b>335.1</b>	<b>114.0</b>	<b>297.2</b>	<b>12.8</b>	<b>38.0</b>

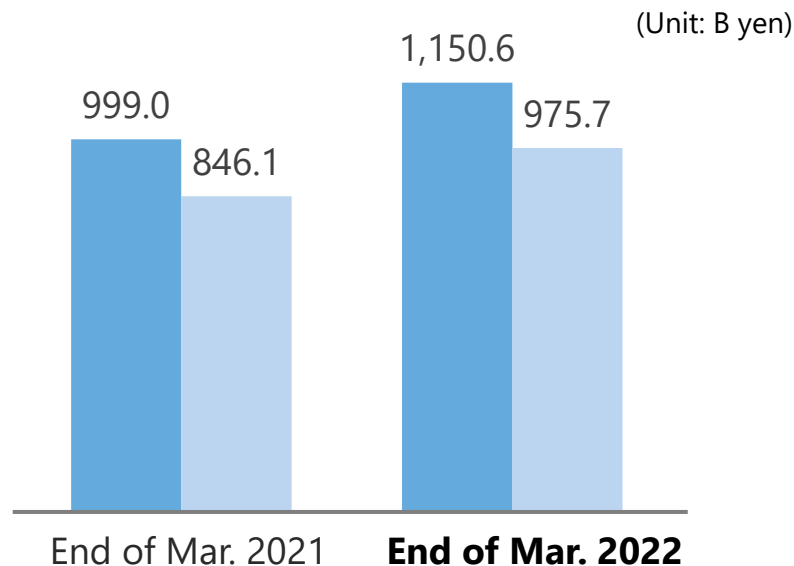
## Main Variation Factors (Year-on-Year Comparison)

- **Prescription drugs**
  - Decrease: Sales of Cymbalta®
- **Overseas subsidiaries/export**
  - US: Increase: Sales of Fetroja®
    - : Received a one-time payment for the transfer of FORTAMET® sales rights
  - EU: Increase: Sales of Fetroja®
- **Contract manufacturing**
  - Increase: The acquisition of Nagase Medicals as a consolidated subsidiary
  - Decrease: Pharmaceutical ingredient export of Xofluza and dolutegravir
- **Royalty income**
  - HIV franchise
    - : Increase: Received a lump sum payment for resolving litigation relating to Biktarvy and dolutegravir patent
    - : Advance royalty income on Biktarvy sales in the U.S. to be received by 2027
  - Crestor®: Decrease: Based on the contract
  - Others: Increase: Out-licensing agreement with ViiV for S-365598

# Financial Position (Consolidated, IFRS)



■ Total Assets   ■ Equity attributable to owners of parent



Unit: B yen		End of Mar. 2021	End of Mar. 2022	Change
Total Assets	Non-current Assets	442.8	491.4	48.6
	Current Assets	556.2	659.2	103.0
Equity attributable to owners of parent		846.1	975.7	129.6
Total Liabilities	Non-current Liabilities	34.3	32.9	△1.3
	Current Liabilities	100.2	124.4	24.2

	End of Mar. 2021	End of Mar. 2022
Ratio of equity attributable to owners of parent to total assets	84.7%	84.8%



# Other Major Progress\*



## • February

- Shionogi has been Selected as one of the "Excellent Integrated Reports" by the GPIF's Domestic Equity Managers for the second consecutive year
- Shionogi has been recognized as one of the highest-ranking companies on the "Supplier Engagement Reporting Leaderboard (Climate Change)" by CDP
- Conclusion of a business cooperation agreement regarding support for children's bright future with the city of Yokohama
- Agreement for enter into a strategic development collaboration for the novel anti-RS virus drug candidate S-337395 with Ube Industries

## • March

- Shionogi received the Special Award in the category of Corporate Environmental Sustainability at the Ministry of the Environment's 3rd ESG Finance Awards Japan
- Started multicenter joint research with XNef, Inc. and Advanced Telecommunications Research Institute International (ATR) on the development of diagnosis and treatment methods in the field of psychiatric disorders
- Filing for approval to manufacture and sell Cefiderocol in Japan

## • April

- Shionogi has been selected for the ESG Investment Index "FTSE Blossom Japan Sector Relative Index" adopted by GPIF
- Shionogi expresses its support for the recommendations of Task Force on Climate-related Financial Disclosures (TCFD) and its participation in the TCFD Consortium
- Agreement for enter into strategic research collaboration for novel hepatitis B therapeutic vaccine with NEC
- Towns Co., Ltd. starts selling the new coronavirus antigen rapid diagnostic kit (Immunoace® SARS-CoV-2 Saliva) \*\*
- Started sales of Symproic® Tablets 0.2mg for the Treatment of Opioid-Induced Constipation in adult patients in Taiwan

# 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.
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