



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. Actions and Financial Forecasts in FY2022 (P.16-29)**
- 3. Shareholder Return (P.31)**



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	335.1	114.0	297.2	12.8	38.0
Operating profit	90.0	110.3	122.6	117.4	(6.1)	(7.1)
Core operating profit*	90.0	110.6	122.9	94.0	17.7	16.6
Profit before tax	115.0	126.3	109.8	143.0	(11.7)	(16.8)
Profit attributable to owners of parent	100.0	114.2	114.2	111.9	2.1	2.3

- **Revenue and profit items reached achieved forecast levels**

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

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

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

* 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	52.5	17.7	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	95.1	32.0	0.1
R&D expenses	18.9	55.5	21.8	54.2	18.3	18.7
Other income & expenses	(2.5)	(1.2)	46.7	22.1	(105.3)	(23.3)
Operating profit	30.6	90.0	110.3	117.4	39.5	(7.1)
Core operating profit*	30.6	90.0	110.6	94.0	31.6	16.6
Finance income & costs	25.0	16.0	63.8	25.6	(37.6)	(9.6)
Profit before tax	39.1	115.0	109.8	143.0	48.1	(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 to support strong sales of Fetroja® and Fetroja®, launch preparation costs for S-217622
- **R&D**
 - Increase: Intensive 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)	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
Total	294.0	335.1	114.0	297.2	12.8	38.0

(Unit: B yen)

Main Variation Factors (Forecast Comparison***)

- **Prescription drugs**
 - Decrease: Sales of Influenza franchise
- **Overseas subsidiaries/export**
 - US/EU: Increase: Sales of cefiderocol (Fetroja®)
 - China: Decrease: Sales on online medical platform lower than projections
- **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
Cymbalta®	17.1	15.9	26.5	(39.9)	(10.6)
Intuniv®	16.6	16.4	13.1	25.4	3.3
Vyvanse®	1.0	0.8	0.3	190.7	0.5
Infectious disease drugs	16.6	11.8	9.8	20.8	2.0
Influenza franchise	7.9	3.1	0.3	-	2.8
OxyContin® franchise	5.0	4.8	5.3	(10.0)	(0.5)
Symproic®	3.1	2.7	2.3	17.9	0.4
Actair®	0.4	0.5	0.3	45.1	0.2
Mulpleta®	0.1	0.1	0.1	8.9	0.0
Pirespa®	3.5	3.8	5.1	(25.3)	(1.3)
Others	30.8	32.4	32.0	1.2	0.4
Crestor®	5.7	5.9	6.7	(11.0)	(0.7)
Irbetan® franchise	3.1	3.2	3.3	(5.0)	(0.2)
Prescription drugs	94.4	89.1	94.7	(5.9)	(5.6)

<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 sales did not reach the forecast due to a very small epidemic of influenza
 - OTC and quasi-drugs did not achieve the forecast due to lower-than-expected 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 supporting strong sales of Fetroja® and Fetcroja®
- **R&D expenses**
 - Due to intensive 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 following 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 to COMIRNATY intramuscular injection (Pfizer) in additional immunological tests

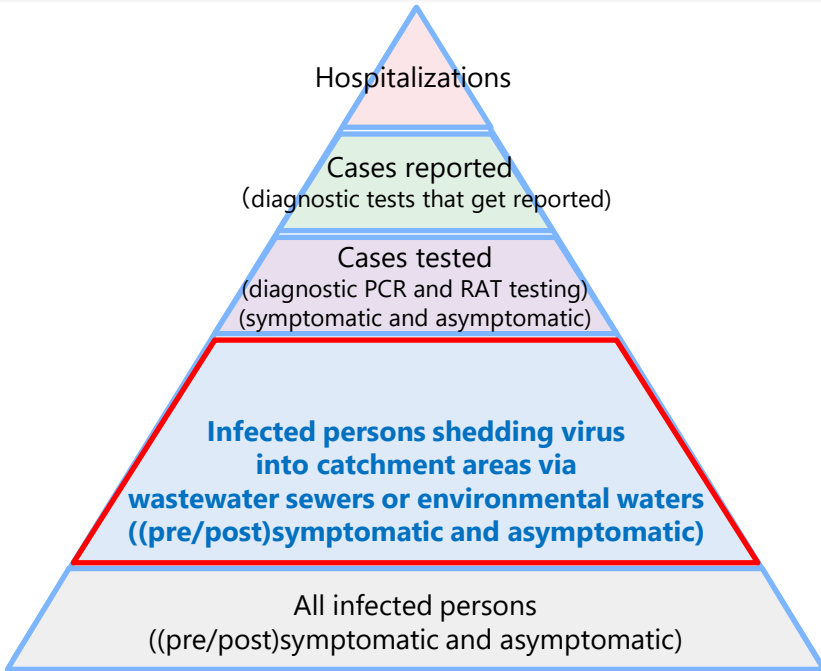
Joint sale of antigen-test kit using saliva specimens

Completion of domestic approval application based on the result of Phase 2a/2b

Ph2 trial started

Although S-217622 and S-268019 were not launched before the end of FY2021, our COVID-19 efforts progressed at a speed that breaks established records

Establishment of AdvanSentinel



※ WHO : Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance*¹

AdvanSentinel

- **Early public health implementation of wastewater monitoring**
 - Partnering with SHIMADZU
 - **Wastewater monitoring is an indispensable method to more accurately assess the infection status of society as a whole, with less risk of selection bias seen with PCR or RAT tests**
 - **US and Europe were progressing this implementation during the COVID-19 pandemic**
 - > US: CDC has been leading wastewater monitoring in 46 states and published the results on a dashboard together with clinical tests²
 - > Europe: All EU Member States have agreed with the European Commission recommendation and around 1370 wastewater treatment plants are under regular surveillance and the data are shared amongst countries³
- **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 new method and kit with very high sensitivity and which can be automated**

By launching a new method with very high sensitivity and automation, we will contribute to the accurate understanding of infection epidemiology worldwide

¹ [Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance \(who.int\)](#)

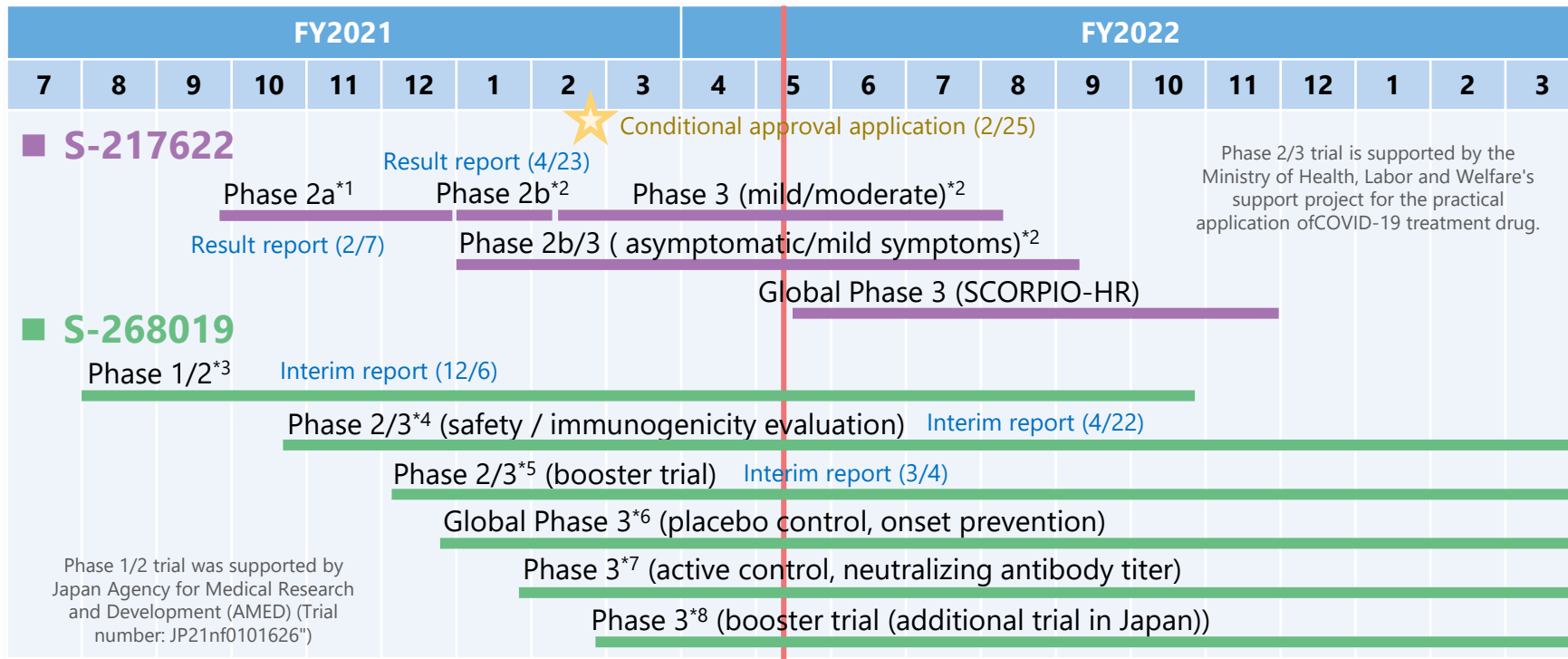
² [National Wastewater Surveillance System \(NWSS\) – a new public health tool to understand COVID-19 spread in a community | CDC](#)

³ [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 results and analysis from Phase 2b part (February 25, 2022)
- **Phase 2b result report**
 - Efficacy and safety results announced at 32nd 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

Preparations are progressing steadily 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 analysis
- **Phase 3 booster trial (additional trial in Japan)**
 - For adults aged 20 to 64 years who received SPIKEVAX (Moderna) twice and elderly people aged 65 years or older who received COMIRNATY or SPIKEVAX twice
 - 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 in support of both initial immunity and booster immunity indications

Results for FY2021 and Issues Remaining



Results for FY2021

Achieved forecasts

**Progress of
COVID-19 related
projects**

**Sophistication
and speed of
decision making**

Issues Remaining

**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**

2. Actions and Financial Forecasts in FY2022

FY2021

Lessons from the special situation of the COVID-19 pandemic

- Promote R&D and production at an unprecedented speed by drastically shifting resources and changing processes
- Efforts to build a sustainable infectious disease business model
- Recommendations for policy changes through the pharmaceutical industry



From FY2022

Apply COVID-19 lessons to drive success and growth

- World-class drug discovery capability with speed, advanced decision-making, and effective resource allocation honed during the COVID-19 situation
- Building the sustainable infectious disease business model
- Further development of vaccine business and of new modalities

Taking the special situation of FY2021 as “the new normal”, promote pandemic experience-based transformation without changing gears

As a result of investments to date
**Realization of returns
from COVID-19 related
projects**

**Developing growth drivers
other than COVID-19
related products**

**Reinvest the profits from COVID-19 related projects and focus on efforts
for medium- to long-term growth**

Investing to address the challenges exposed by the COVID-19 situation

**Enhancement of
vaccine R&D**

**Strengthening the supply
chain (forming of API/
formulation networks)**

**Strengthening bargaining
power with governments/
external support
organizations (securing
specialized human
resources)**

**Building a sustainable infectious disease business foundation
that enables us to globally launch and supply infectious disease drugs on our
own**

Early Commercialization and Value Maximization of COVID-19 Related Products



S-217622 (oral therapeutic drug)

- **Provision in Japan**
 - Domestic manufacturing and marketing approval
 - Formally conclude a purchase contract with the Japanese government and start domestic supply
- **Global provision**
 - Started full-scale purchase negotiations with governments of each country
 - Preparation for access and supply for LMIC* s
- **Lifecycle management**
 - Expansion of indications to pediatric, prophylactic administration, etc.
- **Partnering to support retail (post-governmental) stage of commercialization**



S-268019 (recombinant protein vaccine)

- **Provision use in Japan**
 - Domestic manufacturing and marketing approval
⇒ Construction of a greater than 60 million shots/year production system
- **Lifecycle management**
 - Scheduled to start a trial in 12-19 year old subjects
 - Scheduled to start a trial in 5-11 year old subjects
 - Scheduled to start a booster trial (4th vaccination) mainly for elderly
- **Global provision**
 - Full-scale expansion to Southeast Asia

Promotion of R&D



Promote R&D focusing on COVID-19 related projects, nasal vaccine, 8 core projects

Core pipeline (Blue: 8 core projects*)

Project	Indication
S-217622	COVID-19 treatment
S-268019	COVID-19 vaccine
S-875670	COVID-19 nasal vaccine
S-872600	Influenza nasal vaccine
S-540956	Infectious disease, cancer

Infectious disease

Psycho-neurological diseases

New growth areas

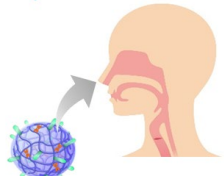
Project	Indication
S-600918 [sivopixant]	Refractory chronic cough
S-812217 [zuranolone]	Depression
BPN14770 [zatolmilast]	Fragile X syndrome
S-531011	Solid tumor
S-005151 [redasemtide]	① Epidermolysis bullosa ② Acute ischemic stroke ③ Knee osteoarthritis ④ Chronic liver disease ⑤ Cardiomyopathy

Accelerate the R&D of growth drivers by leveraging the speed gained from the COVID-19 experience

To Build the Foundation of the Vaccine Business




HanaVax



Cationized nanogel delivery system

A drug discovery venture company originating at the University of Tokyo

 **SHIONOGI**

 **UMN** Addressing Unmet Medical Needs
株式会社UMNファーマ



千葉大学
CHIBA UNIVERSITY

- Able to effectively induce immunity in respiratory mucosa, which is the area that becomes infected, as well as the entire body
- Simple administration with no pain caused by conventional needles
- Utilizing our know-how in developing recombinant protein vaccines using BEVS* and adjuvants, we are considering expansion to other diseases (influenza, pneumococcal bacteria, RS virus, etc.) and development of combination vaccines
- Established the rhabdovirus free ** insect cell culture technology
- Plan to initiate clinical trials for Covid-19 nasal vaccine (S-875670) in FY2022
- Vaccines using BEVS* are widely used, with established efficacy and safety
- Speedy, low cost, and suited to mass production
- Specializes in immunization studies
- Established a joint search department for human mucosal vaccines and opened in April 2022

Strengthen and expand the vaccine business for medium- to long-term growth

Domestic and Overseas Business Initiatives



Domestic business

- **Infectious diseases**
 - Government stockpiling of xofluza and COVID-19 related products in preparation for future pandemics
- **Expansion of CNS projects**
 - **Insomnia treatment drug daridorexant**
 - > Concluded a memorandum of understanding with Mochida regarding a marketing rights license agreement (with certain conditions*) (March 31, 2022)
 - > Development status: Phase 3 (JP)
(US, EU: Approval)

• ADHD

- Intuniv®
- Vivanse®
- SDT-001

• Insomnia

- Insomnia treatment app
 - > Concluded a sales alliance agreement with SUSMED

• Depression

- S-812217

Create synergies with sales products and development compounds

Overseas business

- **COVID-19 related products**
 - Full-scale discussions with stakeholders in each country for commercialization
- **Western business**
 - Maximize the value of Cefiderocol
 - > High economic value evaluation by the National Institute for Health and Care Excellence (NICE)
 - > Collecting and publishing real world data (RWD) evidence in clinical practice
 - > Efforts to improve access
- **China business**
 - Strengthen sales and expand new sales channels after launching products on medical platforms
 - Progression of activities for early launch of new drugs (cefiderocol, naldemedine)
 - Expansion of research approaches utilizing AI technology

Progress of HIV Franchise by ViiV Healthcare



Establishing the long-acting formulation category for both treatment and prevention

- The treatment and prevention markets of long-acting formulations are each expected to grow to the £4-5 billion range by 2030*

Dolutegravir portfolio

Expanding market share of 2-drug regimen

- **Dovato**
 - Acquired the top share in the US and EU switch market
 - Good progress towards achieving sales in excess of £ 1bn in 2022

Cabotegravir portfolio

World's first long-acting formulation

- **CABENUVA (CAB / RPV**)**
 - Treatment once every two months is now possible
 - 1 month oral lead-in is optional
- **Apretude (cabotegravir)**
 - Approved for prophylactic indications once every 2 months

Medium- to long-term growth drivers

Meet a wide range of medical needs

- **S-365598**
 - Aiming to further reduce the burden on patients with an ultra-long-acting formulation that is administered once every 3 months or even less frequently
- **Self-injection regimen**
 - Offering new options with self-managing injections

- **Maximizing the value of dolutegravir portfolio with two-drug regimens**
- **Accelerating the market penetration of long-acting formulations with new Cabenuva labeling, Apretude launch and pursuit of additional regimens**

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



Material goal that Shionogi is committed to address: “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 more responsive regulation 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 to sustain 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 foundation**
 - 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 employment 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 academic research support scheme**
- **Activity details (Annual budget: Around 300 million yen is planned)**
 - Granting subsidies for research on infectious diseases; awards for 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 research progress and the welfare of mankind**

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



Disposal of treasury stock (advantageous issuance)

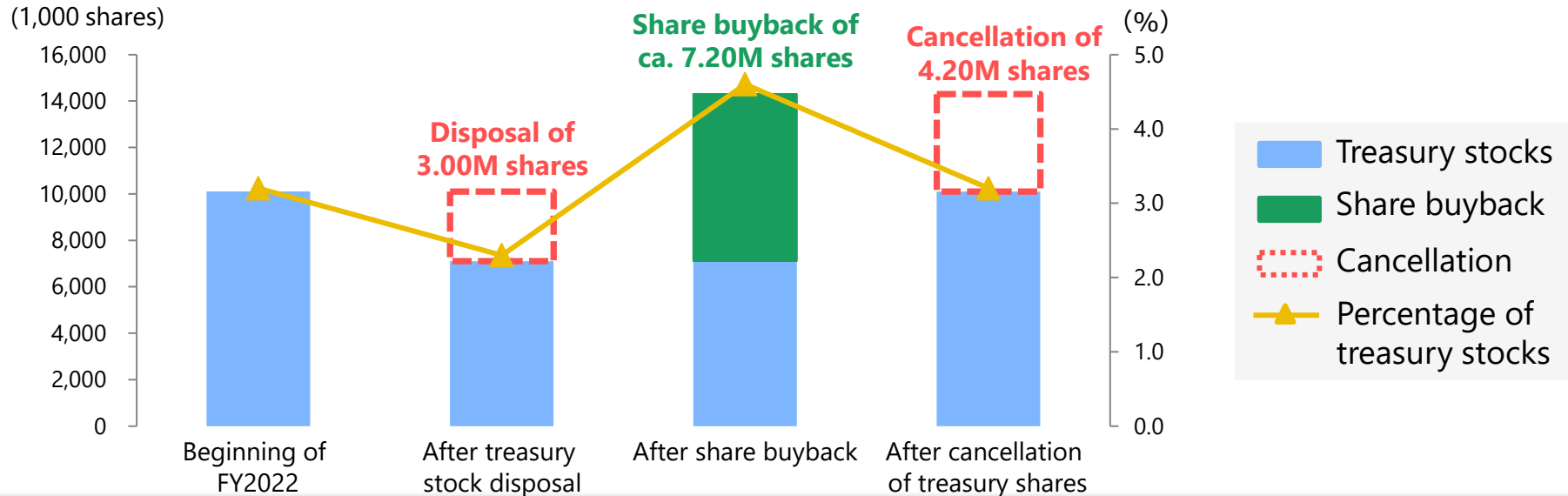
- Total shares to be disposed : 3.00M
- Disposal date: Scheduled to be Decided by the Board of Directors after the general meeting of shareholders scheduled to be held on June 23, 2022

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



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 receive the return from COVID-19 related efforts and reinvest into future growth

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

Statement of Profit or Loss Forecast (Consolidated)



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Cost of Sales	22.0	17.5	16.5		
	88.0	31.5	55.4	58.8	32.6
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Selling, general& administrative expenses	30.0	32.8	28.4		
	120.0	59.0	95.2	26.0	24.8
R&D expenses	17.5	17.8	21.8		
	70.0	32.0	73.0	(4.1)	(3.0)
Other income & expenses	(2.0)	(0.5)	(1.2)	71.5	(0.8)
Operating profit*	30.0	31.7	32.9		
	120.0	57.0	110.3	8.8	9.7
Core operating profit	30.0	31.7	33.0		
	120.0	57.0	110.6	8.5	9.4
Finance income & costs	48.0	29.0	16.0	200.8	32.0
Profit before tax	42.0	47.8	37.7		
	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

(Unit: B yen)

Revenue Forecast by Segment



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

(Unit: B yen)

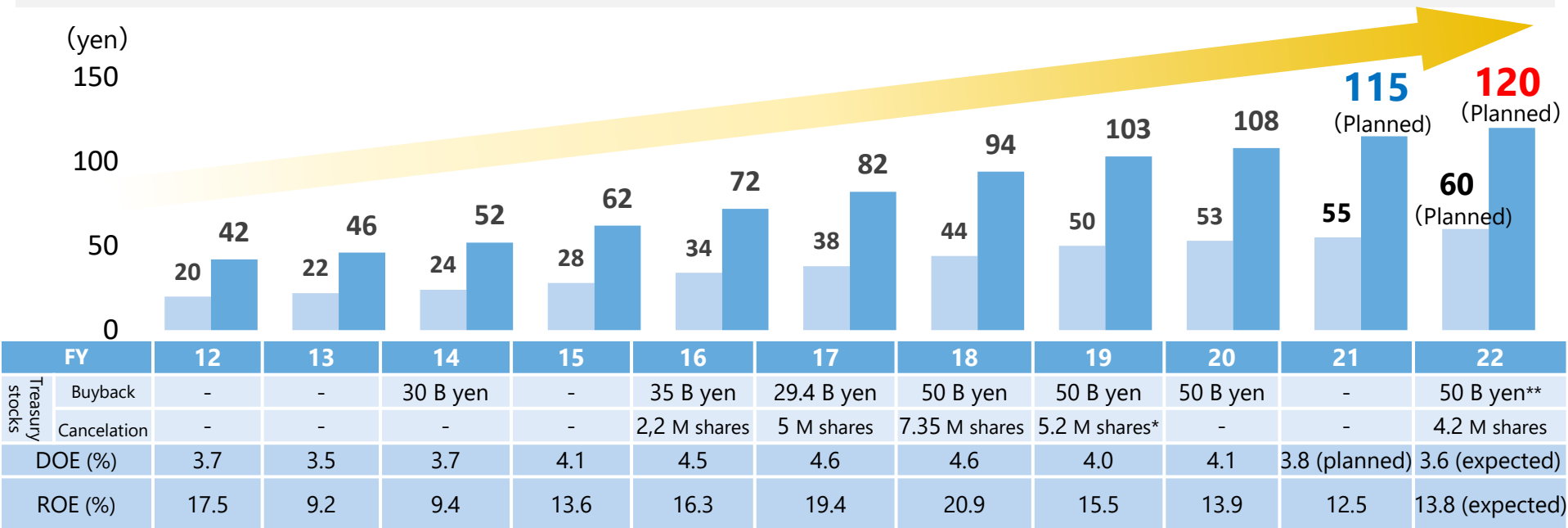
3. Shareholder return

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





Appendix

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)
Prescription drugs	78.6	35.5	89.1	(11.8)	(10.5)

<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
Infectious disease drugs	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)
Others	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)
Prescription drugs	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 of receipt from ViiV of the dividend for 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
Total	294.0	335.1	114.0	297.2	12.8	38.0

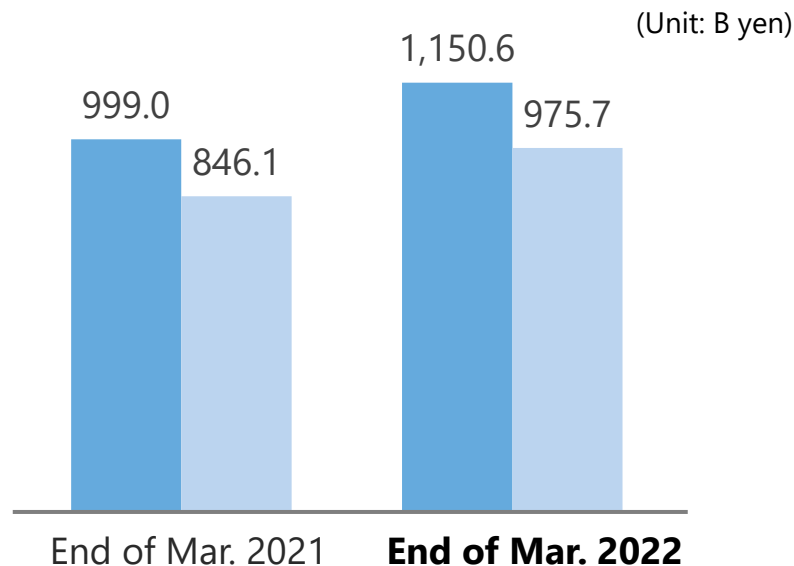
Main Variation Factors (Year-on-Year Comparison)

- **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 bictegravir and dolutegravir patent
: Advance royalty income on bictegravir-containing product 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%

R&D Progress: 8 Core Projects



	Pipeline	Indication	Status
Infectious disease	S-540956	Infectious disease, cancer	Preparing for Phase 1 trial
Psycho-neurological diseases	S-600918 [sivopixant]	①Refractory chronic cough ②Sleep apnea syndrome	①Preparing for Phase 3 trial ②Closed (sufficient effectiveness could not be confirmed)
	S-637880	Neuropathic low back pain	Closed (Due to safety concerns)
	S-812217 [zuranolone]	Depression	Phase 3 trial in progress
	BPN14770 [zatolmilast]	①Alzheimer's disease ②Fragile X syndrome	①Phase 2 trial Closed (Due to safety concerns in this disease) Continued development in Alzheimer's disease ②Phase 2b/3 trial in progress
	S-874713	Psycho-neurological diseases	Preparing for Phase 1 trial
New growth areas	S-531011	Solid tumor	Phase 1b/2 trial in progress
	S-005151 [redasemtide]	①Epidermolysis bullosa ②Acute ischemic stroke ③Knee osteoarthritis ④Chronic liver disease ⑤Cardiomyopathy	①Preparing for additional clinical trial ②Preparing for Phase 3 trial ③④Investigator initiated clinical trial (Phase 2 trial) in progress ⑤Preparing for Investigator initiated clinical trial

Pipeline: Infectious Disease



as of May. 11, 2022



S-872600 Influenza nasal vaccine	S-880008 COVID-19 treatment (peptide)	S-217622 COVID-19 treatment	S-217622* COVID-19 treatment Up
S-875670 Up COVID-19 nasal vaccine	S-540956 Nucleic acid adjuvant	S-268019 COVID-19 Prophylactic vaccine	* Phase 2/3
S-554110 Up Nontuberculous mycobacterial infection	S-337395 Up RSV infectious	S-268019 COVID-19 Prophylactic vaccine	cefiderocol Up Various infectious diseases

: Global development

Out license

S-365598 HIV infection	S-555739 Treatment by suppressing aggravation of COVID-19	Xofluza® Influenza virus infection (Pediatric, < 1 year old)	Xofluza® (US) Influenza virus infection (Pediatric, over 1 year old)
		Xofluza® 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
S-874713 Psycho-neurological diseases	S-600918 [sivopixant] Neuropathic pain	S-600918 [sivopixant] Refractory chronic cough	S-600918 [sivopixant] Refractory chronic cough	S-812217 [zuranolone] Depression
S-109802 Post-stroke spasticity	S-010887 Neuropathic pain	BPN14770 [zatolmilast] Alzheimer's disease	BPN14770 [zatolmilast] Alzheimer's disease	BPN14770** [zatolmilast] Fragile X Syndrome
	S-120083 Inflammatory pain		Rizmoic®* Opioid-induced constipation(pediatric)	SDT-001 Inattentive ADHD (pediatric)
	S-117957 Insomnia		* Phase 1/2	
		S-120083 Inflammatory pain		

: Global development

** Phase 2b/3

Up

Up

Out license

S-0373[rovatirelin]
Spinocerebellar Degeneration

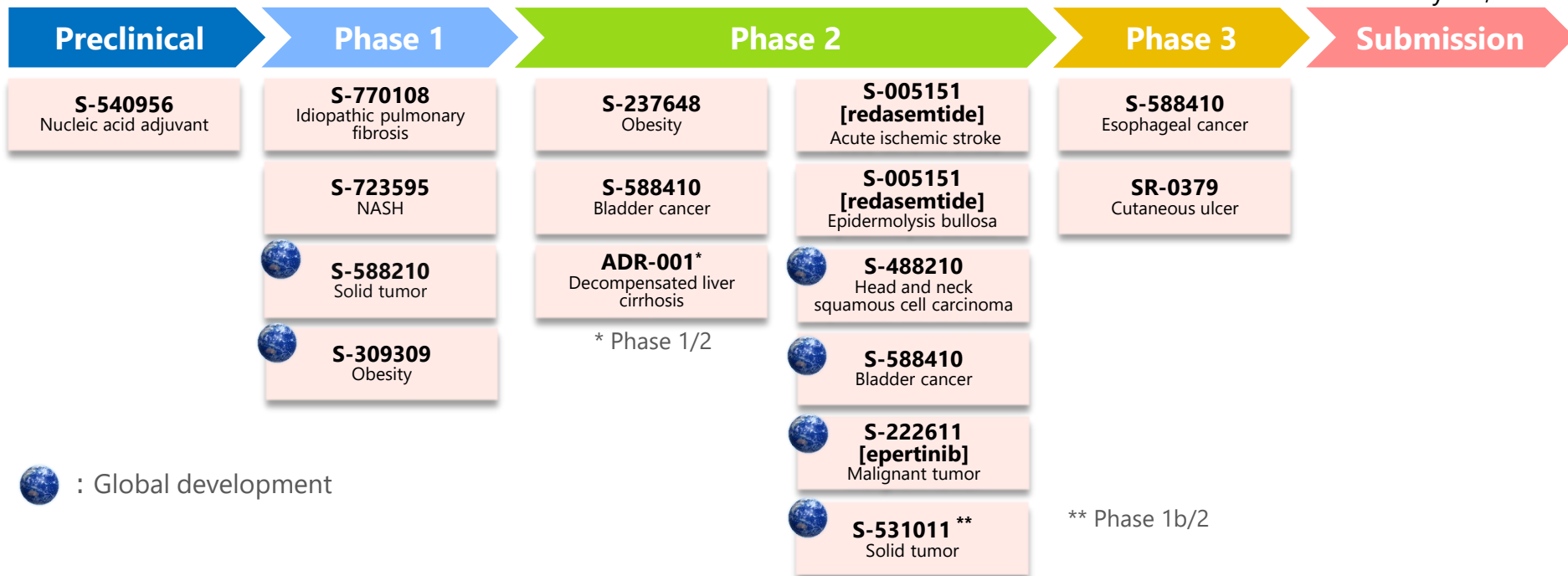
Stage change (Changes from Jan. 31, 2022)


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

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) for the development of diagnosis and treatment methods in the field of psychiatric disorders
- Filed 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 to enter into a strategic research collaboration for a 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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- 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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