1st Quarter of Fiscal 2022 Financial Results

August 1, 2022

Shionogi & Co., Ltd.

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Agenda

1. Overview of Q1 FY2022 Financial Results (P.3-9)
2. Main Activities and Achievements in Q1 FY2022(P.10-15)
3. Actions for Establishment of a Sustainable Infectious Disease Business（P.16-19）
   - Actions for Acute Infectious Disease
   - Progress of HIV Franchise by ViiV Healthcare

1. Overview of Q1 FY2022 Financial Results

Financial Results

(Unit: B yen)

	FY2022				FY2021	Y on Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change (B yen)
	Full year	1H					
Revenue	400.0	180.0	**71.8**	**39.9**	69.0	**4.2**	**2.9**
Operating profit	120.0	57.0	**12.4**	**21.8**	18.8	**(33.9)**	**(6.4)**
Core operating profit*	120.0	57.0	**12.7**	**22.2**	19.4	**(34.7)**	**(6.7)**
Profit before tax	168.0	86.0	**40.3**	**46.9**	22.9	**75.7**	**17.4**
Profit attributable to owners of parent	136.0	71.5	**34.7**	**48.6**	32.2	**7.7**	**2.5**

Revenue, profit before tax, and profit attributable to owners of parent increased year on year while continuing to invest in COVID-19 related projects

Exchange Rate (average)	FY2022 Forecasts	FY2022 Apr.-Jun. results
USD ($) – JPY (¥)	125	129.73
GBP (£) – JPY (¥)	160	163.09
EUR (€) – JPY (¥)	135	138.26

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

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Financial Results
(Excluding forecasts for COVID-19 related products)

Described by excluding the following items from 1H forecast

- Revenue of COVID-19 related products 45 billion yen
- Cost of sales associated with sales of COVID-19 related products

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts 1H	Apr.-Jun. results	Achievement (%)	Apr.-Jun. Results	Change (%)	Change (B yen)
Revenue	135.0	**71.8**	**53.2**	69.0	**4.2**	**2.9**
Operating profit	17.5	**12.4**	**71.0**	18.8	**(33.9)**	**(6.4)**
Core operating profit	17.5	**12.7**	**72.4**	19.4	**(34.7)**	**(6.7)**
Profit before tax	46.5	**40.3**	**86.7**	22.9	**75.7**	**17.4**
Profit attributable to owners of parent	42.0	**34.7**	**82.7**	32.2	**7.7**	**2.5**

Base business excluding revenue from COVID-19 related products progresses steadily against 1H and full year forecasts

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Statement of Profit or Loss

(Unit: B yen)

	FY2022 Forecasts		FY2022		FY2021	Y on Y	
	Full year	1H	Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change (B yen)
Revenue	400.0	180.0	**71.8**	**39.9**	69.0	**4.2**	**2.9**
Cost of Sales	22.0 88.0	17.5 31.5	18.0 **12.9**	**41.1**	17.9 12.3	**5.0**	**0.6**
Gross profit	312.0	148.5	**58.9**	**39.7**	56.6	**4.0**	**2.3**
Selling, general& administrative expenses, R&D expenses total	47.5 190.0	50.6 91.0	63.9 **45.9**	**50.5**	54.1 37.3	**23.2**	**8.6**
Selling, general& administrative expenses	30.0 120.0	32.8 59.0	32.6 **23.4**	**39.7**	32.7 22.6	**3.7**	**0.8**
R&D expenses	17.5 70.0	17.8 32.0	31.4 **22.5**	**70.4**	21.4 14.7	**53.0**	**7.8**
Other income & expenses	(2.0)	(0.5)	**(0.5)**	**107.3**	(0.5)	**(0.9)**	**0.0**
Operating profit	30.0 120.0	31.7 57.0	17.3 **12.4**	**21.8**	27.3 18.8	**(33.9)**	**(6.4)**
Core operating profit	30.0 120.0	31.7 57.0	17.6 **12.7**	**22.2**	28.1 19.4	**(34.7)**	**(6.7)**
Finance income & costs	48.0	29.0	**27.9**	**96.2**	4.1	**572.5**	**23.7**
Profit before tax	42.0 168.0	47.8 86.0	56.1 **40.3**	**46.9**	33.3 22.9	**75.7**	**17.4**
Profit attributable to owners of parent	136.0	71.5	**34.7**	**48.6**	32.2	**7.7**	**2.5**

Main Variation Factors (Y on Y)

- **Revenue**
  - Increase: Domestic sales of Intuniv® and Vyvanse®
    : Sales of Cefiderocol in the US and Europe
    : Royalty income (HIV franchise)
- **R&D**
  - Increase: Investment in R&D activities related to COVID-19
- **Finance income & costs**
  - Increase in income
    : Receipt of dividends from ViiV which was scheduled to be received in 4th quarter of FY2021
    : Increased dividends due to ViiV receipt of lump sum payment from settlement with Gilead
    (Both are transient factors)
- **Profit attributable to owners of parent**

  Received in 1Q of FY2021 refund regarding a favorable Judgement on the complaint for the rescission of tax reassessment by Osaka Regional Taxation Bureau

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Revenue by Segment

(Unit: B yen)

	FY2022 Forecasts Full year	FY2022 Forecasts 1H	FY2022 Apr.-Jun. results	FY2022 Achievement (%)	FY2021 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Prescription drugs	78.6	35.5	**19.0**	**53.5**	23.5	**(19.0)**	**(4.5)**
Overseas subsidiaries/export	41.6	18.1	**8.8**	**48.7**	9.3	**(5.3)**	**(0.5)**
Shionogi Inc.	13.0	6.0	**3.0**	**50.1**	4.7	**(36.2)**	**(1.7)**
Fetroja®	-	-	**1.8**	**-**	1.2	**40.6**	**0.5**
Ping An-Shionogi* /C&O	14.8	6.3	**2.5**	**40.1**	2.4	**7.4**	**0.2**
Shionogi BV(Europe)	8.4	3.4	**1.9**	**55.0**	0.9	**108.6**	**1.0**
Contract manufacturing	14.8	6.3	**3.4**	**53.7**	3.7	**(10.2)**	**(0.4)**
OTC and quasi-drug	13.4	6.3	**1.9**	**30.8**	2.5	**(21.2)**	**(0.5)**
Royalty income	140.4	68.2	**38.4**	**56.3**	29.6	**29.7**	**8.8**
HIV franchise	133.9	67.0	**37.3**	**55.7**	28.8	**29.3**	**8.5**
Crestor®	-	-	**-**	**-**	-	**-**	**-**
Others	6.5	1.2	**1.1**	**91.5**	0.8	**42.6**	**0.3**
COVID-19 related products**	110.0	45.0	**-**	**-**	-	**-**	**-**
Others	1.2	0.6	**0.3**	**51.6**	0.4	**(13.8)**	**(0.1)**
Total	400.0	180.0	71.8	**39.9**	69.0	**4.2**	**2.9**

Main Variation Factors (Y on Y)

- **Prescription drugs**
  - Increase: Sales of Intuniv® and Vyvanse®
  - Decrease: Sales of Cymbalta®
- **Overseas subsidiaries/export**
  - US: Increase: Sales of cefiderocol (Fetroja®)
    : Decrease: Received in 1Q of FY2021 a one-time payment for the transfer of FORTAMET® sales rights, etc. (2.2 B yen)
  - EU: Increase: Sales of cefiderocol (Fetcroja®)
- **Royalty income**
  - HIV franchise

  : Increase: Increase in sales and the impact of foreign exchange

* OTC and quasi-drugs also include in revenue of joint venture ** Revenue from S-217622（Ensitrelvir Fumaric Acid）and S-268019

Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022				FY2021	Y on Y	
	Forecasts		Apr.-Jun.	Achievement	Apr.-Jun.	Change	Change
	Full year	1H	results	(%)	results	(%)	(B yen)
Intuniv®	19.5	9.0	**4.7**	**51.6**	3.6	**29.5**	**1.1**
Vyvanse®	1.1	0.5	**0.3**	**65.0**	0.1	**105.8**	**0.2**
Infectious disease drugs	13.4	4.3	**2.1**	**47.8**	2.1	**(2.3)**	**(0.0)**
Influenza franchise	5.1	0.3	**0.1**	**21.2**	0.0	**108.4**	**0.0**
Cymbalta®	6.1	3.1	**1.7**	**53.8**	6.8	**(75.6)**	**(5.2)**
OxyContin® franchise	4.5	2.3	**1.2**	**52.0**	1.3	**(4.4)**	**(0.1)**
Symproic®	3.3	1.5	**0.8**	**51.9**	0.6	**31.7**	**0.2**
Actair®	0.6	0.3	**0.1**	**45.5**	0.1	**18.0**	**0.0**
Mulpleta®	0.1	0.1	**0.0**	**46.5**	0.0	**(12.4)**	**(0.0)**
Pirespa®	2.4	1.2	**0.7**	**57.5**	1.0	**(29.0)**	**(0.3)**
Others	27.6	13.3	**7.5**	**56.4**	7.9	**(4.4)**	**(0.3)**
Crestor®	3.3	1.7	**1.1**	**62.5**	1.4	**(25.7)**	**(0.4)**
Prescription drugs	78.6	35.5	**19.0**	**53.5**	23.5	**(19.0)**	**(4.5)**

<Products included in infectious disease drugs>

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

Influenza franchise

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Results up to the 1st Quarter and Future efforts

Achievements up to the 1st Quarter

- **Revenue and each profit items excluding COVID-19 related products are steadily progressing against the 1H and full year forecasts**
  - Smooth progress in domestic, overseas business and royalty income
- **Making progress in COVID-19 projects**
  - Started Global Phase 3 of COVID-19 therapeutic
  - Initiated the submission of an application for COVID-19 therapeutic drug

To achieve the full year forecasts

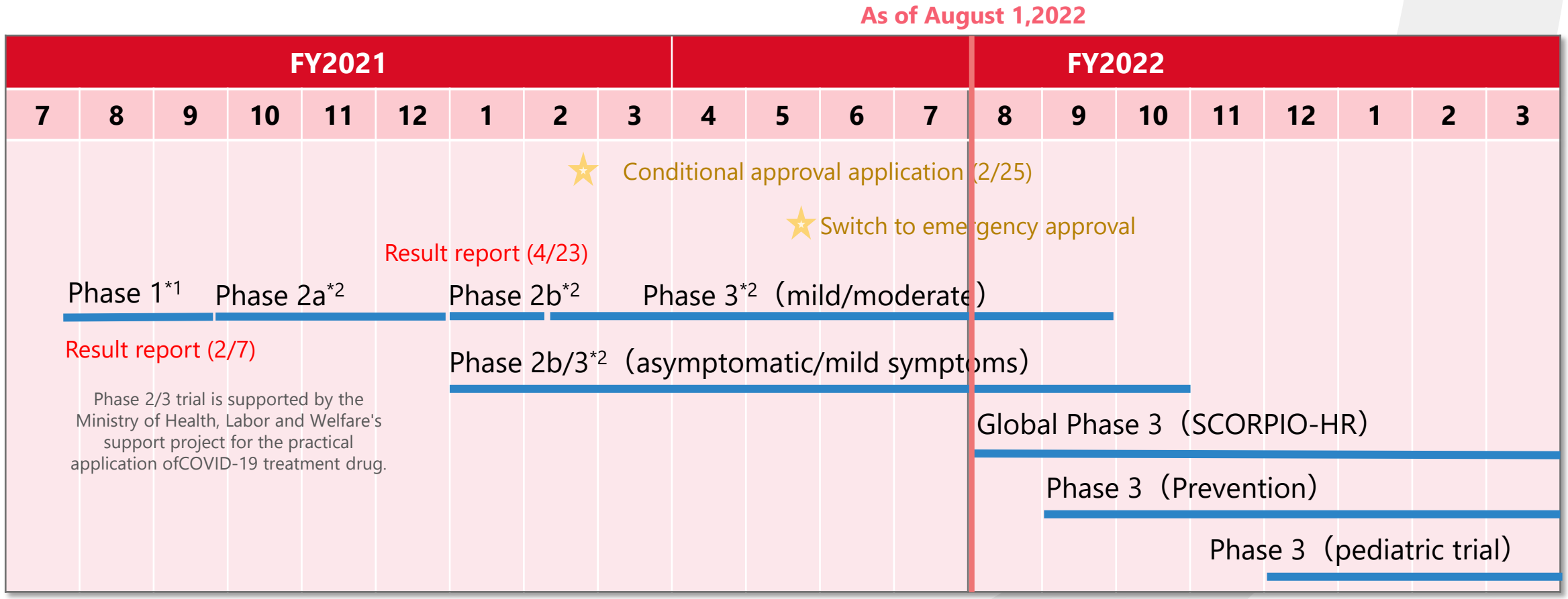
- **There are no revisions to the forecast at this time, and the full-year forecast is expected to be achieved**
- **Maximize the value of COVID-19 related projects**
  - Domestic and Global provision of COVID-19 therapeutic drug
  - Domestic application and provision of COVID-19 vaccine

Achieve full-year forecasts by maximizing the value of COVID-19 related projects, and focus on initiatives for medium- to long-term growth

2. Main Activities and Achievements in Q1 FY2022

Actions for COVID-19 (Therapeutic drug)

Ensitrelvir Fumaric Acid（S-217622）



*1 jRCT2031210202、*2 jRCT2031210350

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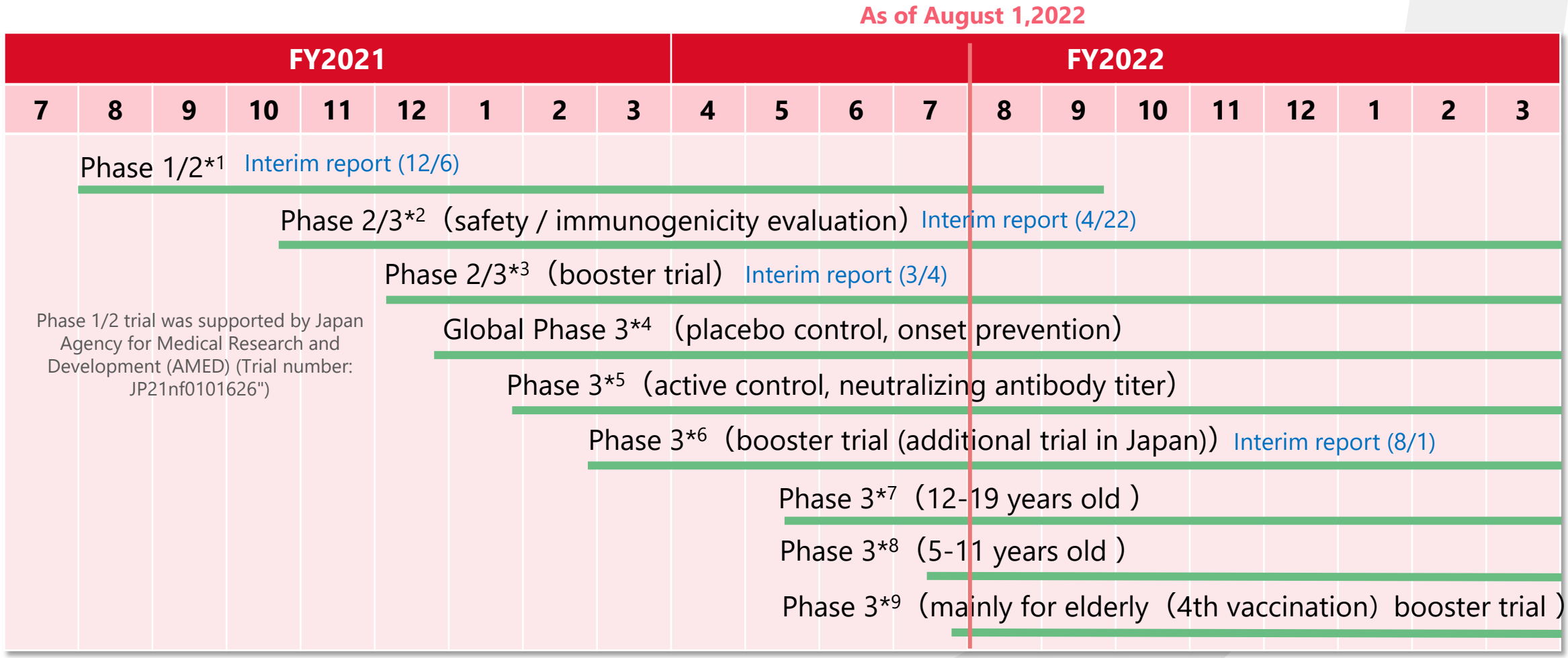
Actions for COVID-19 (Therapeutic drug)

Ensitrelvir Fumaric Acid（S-217622）

- **Provision in Japan**
  - The emergency approval of ensitrelvir was deliberated in the Pharmaceutical Affairs and Food Sanitation Council held on July 20,2022
    - > Continued deliberation based on the progress of Phase 3
- **Continuation of Phase 2/3 trial**
  - Recruitment completed
    - > Phase 3 part (mild / moderate) :1,821cases
    - > Phase 2b/3 part (asymptomatic/mild symptoms) :607cases
  - Top-Line results will be obtained the first half of 2022
- **Global provision after Japan approval**
  - US/EU：Under discussion with FDA,EMA and MHRA for early application with Phase 2/3 trial results
  - China : Ping An-Shionogi Co., Ltd. has initiated the submission of preparatory materials for an application
  - Korea : ILDONG beginning consultation with authorities to apply for approval
- **Lifecycle management**
  - Preparing for the trials to obtain further indications
    - > Prevention of onset after contact with an infected person
    - > Children under 12 years old
- **Global Phase 3 trial**
  - **SCORPIO-HR started**
    - > Patients：SARS-CoV-2 infected patients without hospitalization
  - Considering conducting Phase 3 trials in hospitalized SARS-CoV-2 infected patients
- **Supply**
  - Building a global supply system
    - > Since April 2022, production has been expanding to supply more than 10 million people annually
    - > Plans to manufacture in China and the United States for further supply expansion

Actions for COVID-19 (vaccine)

S-268019 (recombinant protein vaccine)



*1 jRCT2031210269、*2 jRCT2031210383、*3 jRCT2031210470、*4 NCT05212948、*5 jRCT2051210151 、*6 jRCT2031210613、*7 jRCT2031220063、*8 jRCT2011220011、*9 jRCT2031220224

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Actions for COVID-19 (vaccine)

S-268019 (recombinant protein vaccine)

- **Active control, neutralizing antibody titer trial**
  - Superiority verification trial over VAXZEVRIA (AstraZeneca)
    - > Details of the results will be disclosed in paper, etc in 1H FY2022
- **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 (Pfizer) or SPIKEVAX twice
  - Confirmed good efficacy and safety
- **Lifecycle management**
  - Initiated the following 3 trials
    - > The trial in 12-19 years old subjects
    - > The trial in 5-11 years old subjects
    - > The booster trial (4th vaccination) mainly for elderly
- **Provision use in Japan**
  - Scheduled to apply for manufacturing and marketing approval during 1H

Supported by AMED issue number JP21nf0101626 in investigational drug manufacturing in each clinical trial

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Domestic and Overseas Business Initiatives

Domestic business

- **Growth of ADHD franchise contributes to the steady progress of the top line**
  - Intuniv®
    - Growth in the pediatric market
    - Accelerate efforts to increase Intuniv® share of the adult ADHD market
  - Vyvanse®
    - Improve our presence in the ADHD area by deepening understanding of the role of central nervous system stimulants
- **Maximize product value by using digital actions**
- **Strengthening hospital medical representatives**

Overseas business

- **Western business**
  - Maximize the value of Cefiderocol
    - Expansion of sales countries in Europe
    - Efforts to improve global medical access
  - Introducing new growth drivers
- **China business**
  - Efforts to provide S-217622
  - Strengthen sales and expand new sales channels after launching products on medical platforms
  - Progression of activities for early launch of cefiderocol and naldemedine.
  - Expansion of research approaches utilizing AI technology

3. Actions for Establishment of a Sustainable Infectious Disease Business

Actions in Acute Infectious Disease -1-

Building a profit structure that is not influenced by the epidemic

- **Increasing the number of countries adopting delinked/subscription models**
  - Started Cefiderocol subscription model in the UK
    - > Conducting discussions to expand the number of countries using this model, mainly in Europe
- **Government purchasing / stockpiling**
  - Addition of Xofluza® to domestic stockpile
    - > Under discussions regarding purchase volume and amount

Improving drug access globally

- **Concluded a partnership agreement with GARDP and CHAI**
  - Activities to provide Cefiderocol to 135 countries including low- and middle-income countries
    - > SHIONOGI : Providing Cefiderocol licenses and production know-how
    - > GARDP* : Sublicense agreements with drug substance manufacturers, drug developers, and wholesalers for LMIC
    - > CHAI** : Support for application to regulatory agencies in each country, support for manufacturer selection and technology transfer

⇒ **Acquiring capabilities to deliver products globally, including LMIC**

* GARDP：Global Antibiotic Research and Development Partnership
** CHAI：Clinton Health Access Initiative

Actions in Acute Infectious Disease -2-

Execution of a license agreement for a new antifungal agent olorofim* (F2G)

- **Therapeutic challenges for invasive aspergillosis**
  - Mortality approaches 100% without effective treatment**
    - Existing therapies have severe limitations including toxicity, resistance, and drug-drug interactions
- **Expectations for olorofim**
  - Oral preparation with a new mechanism of action different from existing drugs
  - Global Phase 3 trial ongoing
- **Commercial strategy**
  - Synergies with information provision activities regarding cefiderocol
    - High presence cultivated in the area of severe infectious diseases
    - Efficient sales activities due to overlap of most target facilities and doctors
  - Expansion in marketable Europe and China (Asia)

By aggressively investing in fungal diseases with high unmet medical needs, strengthen infectious disease business in Europe and China, and accelerate medium- to long-term growth of overseas business

* Part of strategic business investment in the medium-term business plan "Shionogi Transformation Strategy (STS2030)
** Lancet. 2016;387:760–769, N Engl J Med 2002; 347:408-415, Clin. Infect. Dis. 2010;50:1091–1100

Progress of HIV Franchise by ViiV Healthcare

Driving growth of innovative products: Dovato and cabotegravir

- **Dovato (Two-drug regimen)**
  - Reached rolling 12-months £1bn sales milestone
- **Cabenuva (Long-acting formulation: Treatment)**
  - Sales doubled versus Q1 2022
    - Driven by launch of every eight weeks dosing and optional oral lead-in
- **Apretude (Long-acting formulation: Prevention)**
  - Showed new positive results from the HPTN 084 study* at AIDS 2022**
    - 89% more preventive effect than daily pills even 1 year after administration
    - Confirmed safety for pregnant women

* About HPTN 084 (NCT03164564)
The trial is designed to evaluate the safety and efficacy of the cabotegravir LA for HIV prevention compared to daily oral FTC/TDF tablets in 3,224 cisgender women in sub-Saharan Africa who are at increased risk of HIV acquisition

** 24th International AIDS Conference

On track to forecasts due to growth of dolutegravir portfolio with two-drug regimens and accelerated uptake of long-acting formulations

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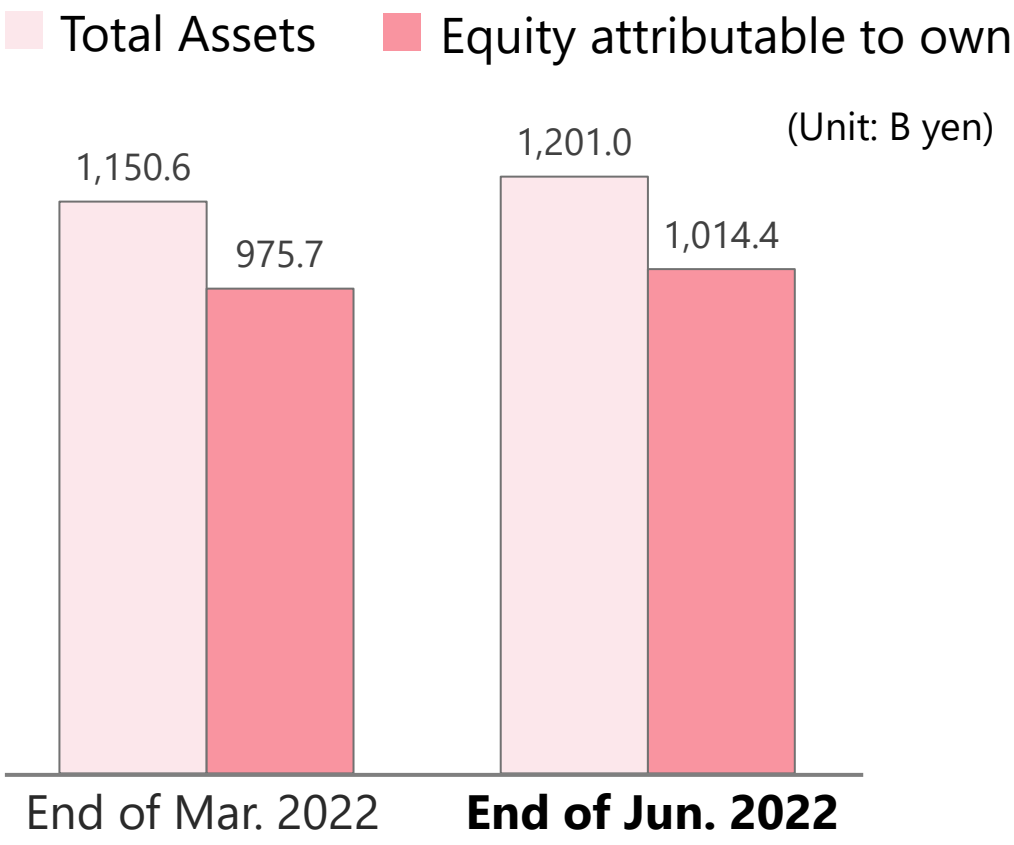
Appendix

Financial Position (Consolidated, IFRS)



	End of Mar. 2022	End of Jun. 2022
Ratio of equity attributable to owners of parent to total assets	84.8%	84.5%

Unit: B yen		End of Mar. 2022	End of Jun. 2022	Change
Total Assets	Non-current Assets	491.4	517.0	25.6
	Current Assets	659.2	683.9	24.7
Equity attributable to owners of parent		975.7	1,014.4	38.7
Total Liabilities	Non-current Liabilities	32.9	34.6	1.7
	Current Liabilities	124.4	129.8	5.4

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Pipeline: 8 Core Projects

	Pipeline	Indication	Status
Infectious disease	**S-875670**	COVID-19 nasal vaccine	Preclinical trial in progress
	S-872600	Influenza nasal vaccine	Preclinical trial in progress
	S-540956	Infectious disease, cancer	Preparing for Phase 1 trial
Psycho-neurological diseases	**S-600918 [sivopixant]**	Refractory chronic cough	Preparing for Phase 3 trial
	S-812217 [zuranolone]	Depression	Phase 3 trial in progress
	BPN14770 [zatolmilast]	Fragile X syndrome	Phase 2b/3 trial in progress
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	①Initiated additional clinical trial ②Preparing for Phase 3 trial ③④Investigator initiated clinical trial (Phase 2 trial) in progress ⑤Preparing for investigator initiated clinical trial

Shionogi will describe in detail at R&D day (September 22, 2022)

Pipeline: Infectious Disease

as of August. 1, 2022

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-872600 Influenza nasal vaccine	**S-880008** COVID-19 treatment (peptide)		**S-217622*** **[Ensitrelvir Fumaric Acid]** COVID-19 treatment	**S-217622*** **[Ensitrelvir Fumaric Acid]** COVID-19 treatment
S-875670 COVID-19 nasal vaccine	**S-540956** Nucleic acid adjuvant		**S-268019** COVID-19 Prophylactic vaccine	* Phase 2/3
S-554110 Nontuberculous mycobacterial infection	**S-337395** RSV infections		**S-268019** COVID-19 Prophylactic vaccine	**cefiderocol** Various infectious diseases
			cefiderocol Aerobic Gram-negative bacterial infection（Pediatric）	**Xofluza®** Influenza virus infection (Granules, < 20kg)
			F901318 **[olorofim]** Invasive Aspergillosis	

: 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®
Influenza virus infection
(Transmission)

Xofluza®（US）
Influenza virus infection
(Pediatric, < 1year old)

Stage change（Change from May. 11, 2022）
F901318（Invasive Aspergillosis ）：Co-development with F2G

: Progress from May. 11, to August. 1, 2022

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Pipeline: Psycho-neurological Disease

as of August. 1, 2022

Preclinical	Phase 1	Phase 2	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-151128 Chronic pain	**S-120083** Inflammatory pain		**Rizmoic*** Opioid-induced constipation (pediatric)	**SDT-001** Inattentive ADHD (pediatric)	
	S-117957 insomnia				

** Phase 2b/3

* Phase 1/2

: Global development

Out license

S-0373 [rovatirelin]
Spinocerebellar Degeneration

Stage change (change from May. 11, 2022)
S-151128（Chronic pain）: Preclinical

: Progress from May. 11, to August. 1, 2022

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Pipeline: New Growth Areas

as of August. 1, 2022

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-770108** Idiopathic pulmonary	**S-237648** Obesity	**S-005151 [redasemtide]** Acute ischemic stroke	**S-588410** Esophageal cancer
	S-588210 Solid tumor	**S-588410** Bladder cancer	**S-005151 [redasemtide]** Epidermolysis bullosa	**SR-0379** Cutaneous ulcer
	S-309309 Obesity	**ADR-001*** Decompensated liver cirrhosis	**S-488210** Head and neck squamous cell carcinoma	
			S-588410 Bladder cancer	
			S-222611 [epertinib] Malignant tumor	
			S-531011** Solid tumor	

* Phase 1/2

** Phase 1b/2

: Global development

Out license

S-723595
NASH

Stage change (change from May. 11, 2022)
S-723595（NASH）: out license

: Progress from May. 11, to August. 1, 2022

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Other Major Progress*

- **May**
  - Conclusion of license agreement for the novel NASH drug candidate S-723595 and the ACC inhibitor program with TLC**
    - > Shionogi will receive an upfront payment and milestones, royalty by granting rights to develop and commercialize S-723595
- **June**
  - Initiation of Crowdfunding for the communication barrier free project
  - Conclusion of a basic agreement between Pixie Dust Technologies and Shionogi for joint research for improvement of cognitive function and brain activation by sound stimulation
  - Shionogi Selected as a Member of the "SOMPO Sustainability Index" for the 11th Consecutive Year
  - The Inclusion of Universal Antigen Vaccine Research into the Vaccine / New Modality Research and Development Project following a Public Solicitation by SCARDA
- **July**
  - The Launch of the new SHIONOGI Group Brand
  - Execution of sublicense agreement with JEIL regarding development and commercialization of cefiderocol in South Korea

* Progress from May. 12. 2022 to August. 1. 2022 ** TLC：The Liver Company Inc.

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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