



FY2020 Financial Results

(April 2020 – March 2021)

May 10, 2021

Isao Teshirogi, Ph.D.
President and CEO



Agenda



- 1. Overview of FY2020 Financial Results (P.4-13)**
- 2. Actions and Financial Forecasts in FY2021 (P.15-27)**
- 3. Shareholder Return (P.29)**

1. Overview of FY2020 Financial Results

Financial Results (Consolidated)



(Unit : B yen)

	FY2020			FY2019	Y on Y	
	Forecasts (Revised on Feb. 1)	Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Revenue	301.4	297.2	98.6	333.4	(10.9)	(36.2)
Operating profit	122.9	117.4	95.6	130.6	(10.1)	(13.2)
Core operating profit**	97.7	94.0	96.1	127.4	(26.2)	(33.4)
Profit before tax	149.3	143.0	95.8	158.5	(9.8)	(15.5)
Profit attributable to owners of parent	113.7	111.9	98.4	122.2	(8.5)	(10.3)

- Sales and profits decreased due to shrinking of the pharmaceutical market by COVID-19 and exchange rate impact on royalty income
- Sales of domestic prescription drugs failed to meet revised forecast
- Aggressive investment in R&D and new businesses by redirecting sales activity costs

Exchange Rate (average)	FY2020 forecasts (Feb. 1)	FY2020 results	FY2019 results
USD (\$) – JPY (¥)	105.50	106.11	108.72
GBP (£) – JPY (¥)	137.50	138.75	138.15
EUR (€) – JPY (¥)	123.00	123.76	120.82

* Converted from JGAAP to IFRS

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

Statement of Profit or Loss (Consolidated)



(Unit: B yen)

	Forecasts (Revised on Feb. 1)	FY2020		FY2019	Y on Y	
		Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Revenue	301.4	297.2	98.6	333.4	(10.9)	(36.2)
Cost of sales	18.1 54.5	17.7 52.5	96.4	17.0 56.8	(7.5)	(4.3)
Gross profit	246.9	244.7	99.1	276.6	(11.5)	(31.9)
Selling general & administrative expenses	31.3 94.4	32.0 95.1	100.8	29.5 98.4	(3.3)	(3.2)
R&D expenses	17.3 52.0	18.3 54.2	104.3	14.4 47.9	13.1	6.3
Other income	25.5	26.4	103.5	4.3	515.3	22.1
Other expenses	3.1	4.3	137.3	4.0	7.7	0.3
Operating profit	40.8 122.9	39.5 117.4	95.6	39.2 130.6	(10.1)	(13.2)
Core operating profit**	32.4 97.7	31.6 94.0	96.1	38.2 127.4	(26.2)	(33.4)
Finance income	28.3	26.5	93.7	30.5	(13.1)	(4.0)
Finance costs	1.9	0.9	49.4	2.6	(64.0)	(1.7)
Profit before tax	49.5 149.3	48.1 143.0	95.8	47.5 158.5	(9.8)	(15.5)
Profit attributable to owners of parent	113.7	111.9	98.4	122.2	(8.5)	(10.3)

* Converted from JGAAP to IFRS

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

Main Variation Factors (Statement of Profit or Loss)



• Y on Y comparison

(Unit: B yen)

Revenue	(36.2)
Cost of sales	(4.3)
Gross profit	(31.9)
Selling general & administrative expenses	(3.2)
R&D expenses	6.3
Other income	22.1
Other expenses	0.3
Operating profit	(13.2)
Core operating profit**	(33.4)
Finance income	(4.0)
Finance costs	(1.7)
Profit before tax	(15.5)
Profit attributable to owners of parent	(10.3)

Decrease in profit Increase in profit

Main Variation Factors (Y on Y)

• Revenue

- Decrease in domestic prescription drugs business
- Decrease in overseas business (US: one-time payment received in FY2019)
- Decrease in royalty income

• Cost of sales

- Increase in OTC and quasi-drugs and contract manufacturing revenue from the business combination of Nagase Medicals
- Decrease due to reduced prescription drug sales

• Selling general & administrative expenses

- Decrease in visits to medical institutions and utilization of e-detailing

• R&D expenses

- Aggressive investment in COVID-19-related projects
- Accelerating progress of 8 core projects*

• Other income

- Gain on exchange of Shionogi Shibuya Building

Main Variation Factors (revised budget on Feb. 1)

• Revenue

- Not achieved for domestic prescription drugs (-3.7 B yen)

• R&D expenses

- Increased due to investment in core 8 projects (+2.3 B yen)

Revenue by Segment



(Unit: B yen)

	Forecasts (Revised on Feb. 1)	FY2020		FY2019	Y on Y	
		Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Domestic Prescription drugs	98.3	94.7	96.3	106.3	(10.9)	(11.6)
Overseas subsidiaries/export	24.5	24.6	100.5	30.8	(20.0)	(6.2)
Shionogi Inc.	7.0	7.5	107.0	10.1	(26.3)	(2.7)
Fetroja®**	—	1.7	—	0.0	—	1.6
C&O	10.1	10.1	99.8	13.1	(23.3)	(3.1)
Contract manufacturing	19.0	19.7	104.1	17.6	12.3	2.2
OTC and quasi-drug	11.9	11.7	98.7	9.7	20.7	2.0
Royalty income	146.2	144.6	98.9	166.9	(13.3)	(22.2)
HIV franchise	124.3	123.4	99.2	128.1	(3.7)	(4.7)
Crestor®	16.9	16.6	98.1	22.3	(25.7)	(5.7)
Others	5.0	4.7	94.4	16.5	(71.5)	(11.8)
Others	1.5	1.8	114.7	2.2	(18.5)	(0.4)
Total	301.4	297.2	98.6	333.4	(10.9)	(36.2)

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	Forecasts (Revised on Feb. 1)	FY2020		FY2019	Y on Y	
		Results	Achievement (%)	Results*	Change (%)	Change (B yen)
Cymbalta®	27.4	26.5	96.4	26.2	0.9	0.2
Intuniv®	14.0	13.1	93.6	10.6	22.8	2.4
Vyvanse®**	0.5	0.3	59.7	0.0	—	0.3
Infectious disease drugs	10.6	9.8	91.8	16.0	(39.1)	(6.3)
Influenza franchise	0.7	0.3	35.7	2.4	(89.1)	(2.1)
OxyContin® franchise	5.5	5.3	96.3	5.8	(8.7)	(0.5)
Symproic®	2.3	2.3	98.3	2.1	6.8	0.1
Actair®	0.3	0.3	101.7	0.3	25.3	0.1
Mulpleta®	0.1	0.1	85.0	0.1	(23.4)	(0.0)
Pirespa®	5.2	5.1	97.7	6.8	(24.3)	(1.6)
Others	32.3	32.0	98.9	38.3	(16.4)	(6.3)
Crestor®	6.9	6.7	97.1	8.6	(22.4)	(1.9)
Irbetan® franchise	3.4	3.3	97.7	4.2	(21.2)	(0.9)
Prescription drugs	98.3	94.7	96.3	106.3	(10.9)	(11.6)

<Products included in infectious disease drugs>

• Xofluza®
• Rapiacta®
• Brightpoc® Flu・Neo

• FINIBAX®
• Flumarin®
• Flomox®

• Ceftem®
• Shiomarin®
• Vancomycin

• Baktar®
• Flagyl®
• Fluconazole

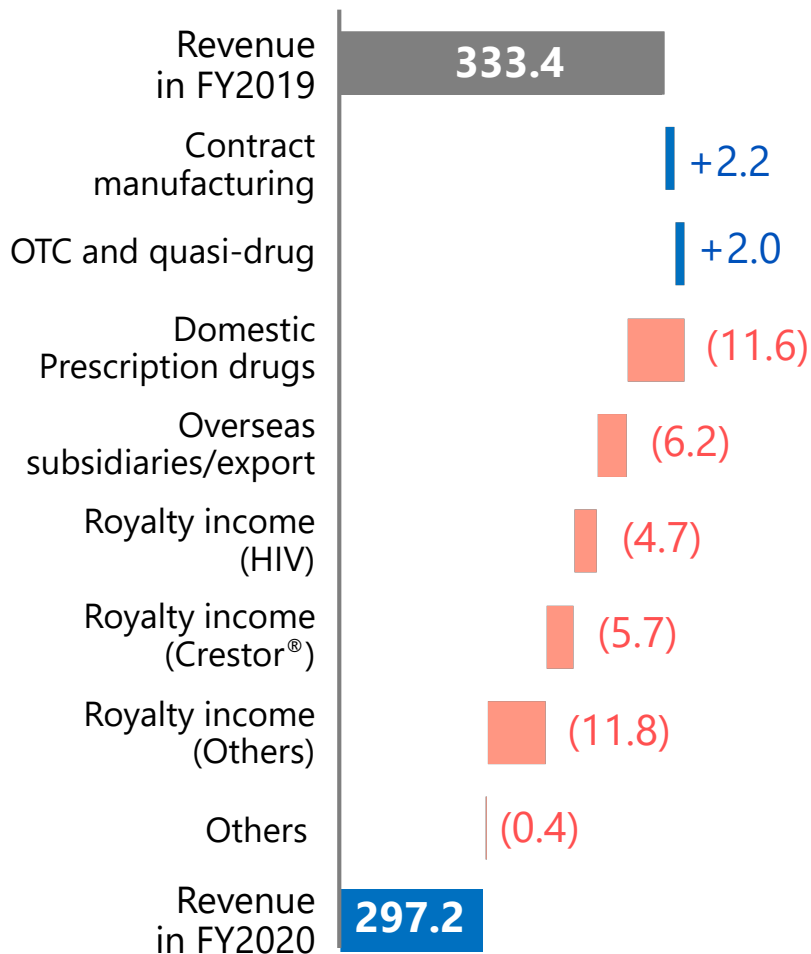
• ISODINE®

Main Variation Factors (Revenue by Segment)



• Y on Y comparison

(Unit: B yen)



Main Variation Factors (Y on Y)

• Domestic Prescription drugs

- Increase in sales of Intuniv®
- Decrease in sales of infectious disease drugs and impact of price revision

• Overseas subsidiaries/export

- US: Fetroja® sales more than projected
: Decrease due to one-time payment received from BDSI* for Symproic® (Received in FY2019)
- China: Decrease in sales of rabeprazole

• Contract manufacturing

- Increase of contract manufacturing revenue of Nagase Medicals

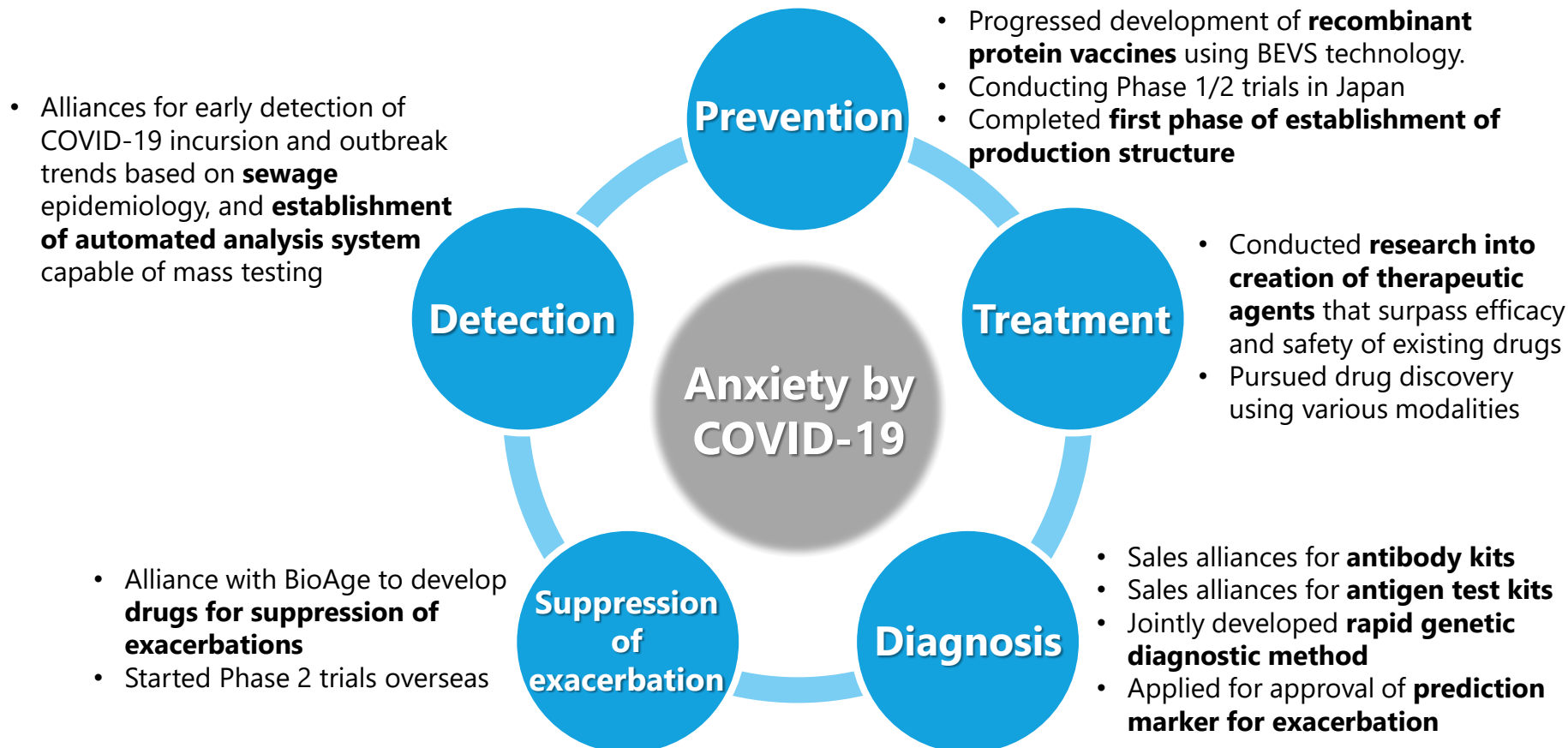
• OTC and quasi-drug

- Increase of infectious disease-related products and release of RINDERON®

• Royalty income

- Exchange rate impact on royalty income from HIV franchise (£ / \$)
> Temporary increase in demand at the start of COVID-19 in 4Q of FY2020
- Decrease in royalty income of Crestor® from Jan. 2021 based on the contract
- Decrease due to one-time payment received from Roche for Xofluza® (received in FY2019)

Action for total care of COVID-19



Aggressive resource commitment to contribute to the restoration of safety and security to society

Actions and Achievements in FY2020

Promotion of R&D : Core 8 Projects



	Pipeline	Indication	Initial target for FY2020	Status
Infectious disease	S-540956	HIV infection, cancer	Initiation of Phase 1 study in 4Q FY2020	Changed to 1Q FY2021
Psycho-neurological diseases	S-600918	①Refractory chronic cough ②sleep apnea syndrome	①Phase 2b topline results are anticipated in 1Q FY2021 ②Phase 2a topline results (Japan) are anticipated in 1Q FY2021	①②On schedule
	S-637880	Neuropathic low back pain	Phase 2a topline results (Japan) are anticipated in 1Q FY2022	On schedule
	zuranolone [S-812217]	Depression	Phase 2 topline results (Japan) are anticipated in 3Q FY2021	Topline results are anticipated in 2Q FY2021 (3M ahead of schedule)
	BPN14770	①Alzheimer's disease ②Fragile X Syndrome	①Initiation of Phase 2 study (Japan) in 2Q FY2021 ②Initiation of Phase 3 study in FY2Q 2021	①Phase 2 study started in 1Q FY2021 (3M ahead of schedule) ②On schedule
	S-874713	Psycho-neurological diseases	Initiation of Phase I study in 4Q FY2020	Changed to 2Q FY2021
New growth areas	S-531011	Solid tumor	Initiation of Phase I study in 2Q FY2021	On schedule
	redasemtide [S-005151]	①Epidermolysis bullosa ②Acute stroke ③Osteoarthritis ④Chronic liver disease	①Preparing for application ②Phase 2 topline results (Japan) are anticipated in 3Q FY2021 ③④Phase 2 in progress (Japan) (Investigator initiated clinical trial)	①On schedule ②③④On schedule

Steady progress along with COVID-19-related projects, with some plans ahead of schedule*

Actions and Achievements in FY2020

Progress in Overseas Business



US and Europe: Maximized value of cefiderocol

- **Promote both antimicrobial stewardship and infectious disease business growth**
 - US: Additional indication approval and designation for NTAP*
 - Europe: Sales growth in 5 countries (UK, Sweden, Germany, France, and Austria)
 - > Adopted for subscription-type reimbursement model in the UK of up to £10 million per year per product (payment contracts to begin in April 2022)
 - > Started supply as a delinked incentive model with guaranteed minimum payment in Sweden.

China: Ping An-Shionogi's business transformation

- **Completed establishment of Ping An-Shionogi** (Hong Kong: Aug.2020, Shanghai: Nov.2020)
 - Pharmaceutical sales: Started to supply products via Ping An Group's online treatment platform
 - New drug development: Advanced preparations for early approval of cefiderocol and naldemedine



Steady progress in Western and Chinese businesses

Progress of business transformation in FY2020

**Advancement of
core 8 projects**

**Actions for
total care of
COVID-19**

**Growth of
overseas
business**

In COVID-19-related R&D, we were unable to respond to the expectations of society as a leading company of infectious diseases

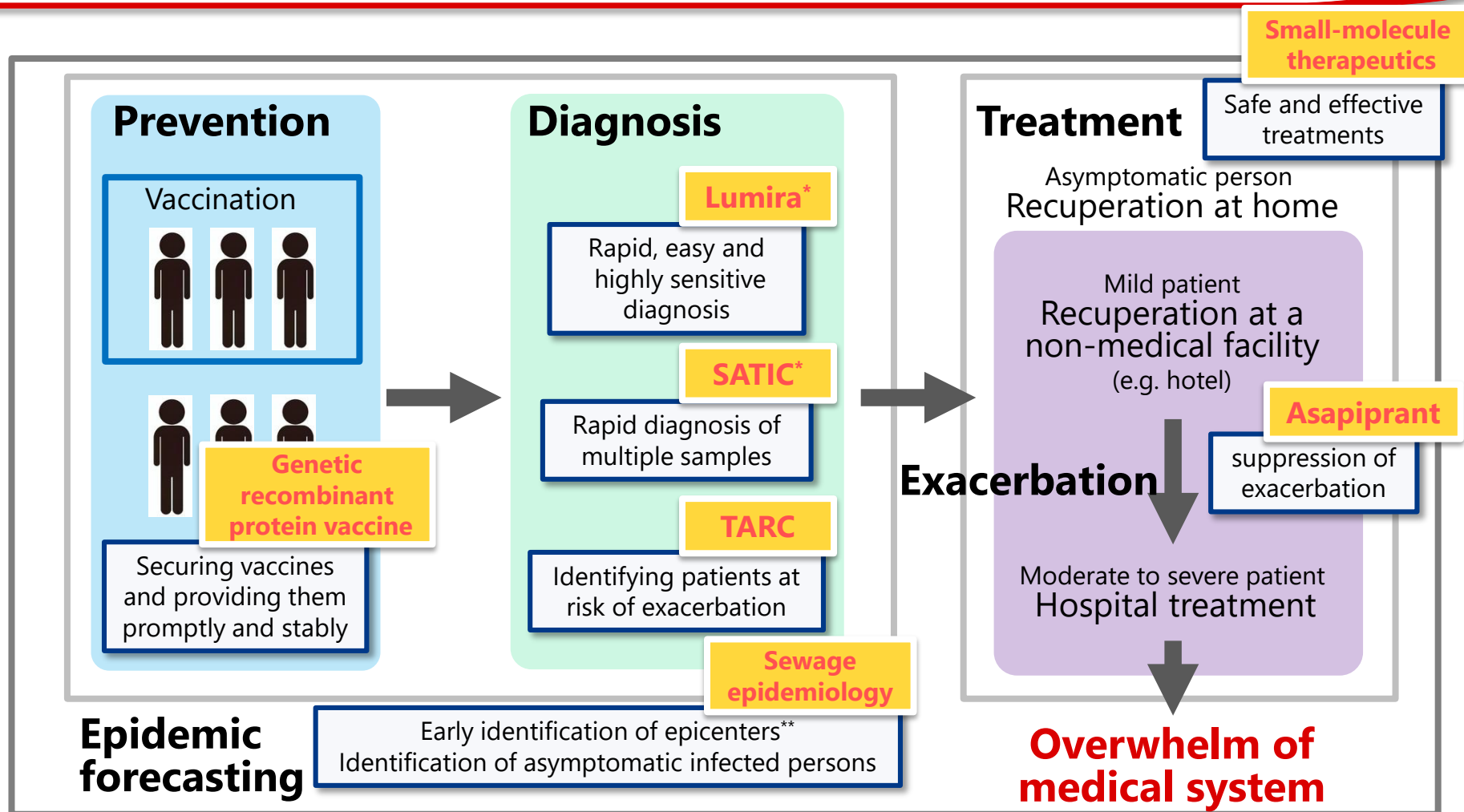
In FY2021, Shionogi will continue its efforts to provide solutions related to COVID-19 and contribute to the restoration of the safety and security of society

2. Actions and Financial Forecasts in FY2021

As a leading company in the infectious disease field

**Shionogi will work intensively to counter the
COVID-19 pandemic as our highest priority**

Current Issues and What Shionogi Wants to Achieve



Providing solutions for the overwhelmed medical system

As society's need for an early end to the pandemic grows ever greater, the business environment is changing at an unprecedented speed

Vaccines

Hopes for a purely domestic vaccine

- ⇒ Expectations for domestic vaccines due to prolonged COVID-19 and widespread epidemic of mutant virus
- ⇒ Active discussions on reviewing the existing approval system in case of emergency response (EUA*-like system, etc.)

Therapeutic drugs

Hopes for new drugs that can end the pandemic

- ⇒ Signs of changes in current treatment indicators (symptom improvement ⇒ viral load reduction, etc.)
- ⇒ Possibility of using a conditional early approval system, etc.

Diagnosis

Diagnostic methods to reduce pressure on the medical system

- ⇒ Increasing need for diagnostics that allow patient triage, such as exacerbation markers
- ⇒ Expand to simultaneous diagnosis of flu and COVID-19

Epidemic detection and forecasting

Balancing infection control and economic activity

- ⇒ Increased focus on efforts to implement sewage epidemiology

Development and Stable Supply of Domestic Vaccines



Actions for the introduction of purely domestic vaccines

Development / production status

- **Conducting Ph1/2 trials in Japan**
 - Confirmed no major safety concerns
 - Preparing for Ph3 trials to start by end of year.
- **Production structure established**
 - Moving to second phase of construction to increase production



Vaccine production facility newly established at UNIGEN

Key factors influencing launch date

- Difficulty in conducting large-scale clinical trials worldwide
- A large blue arrow pointing downwards, indicating a flow or consequence from the first factor to the subsequent ones.
- Started discussion on **alternative methods to evaluate efficacy and safety**
 - Increasing debate about **the flexible operation of the current approval system**

Continue to build evidence, increase production, and discuss with regulators and ministries to allow availability later in CY2021

Development of Therapeutic Drugs with Superior Efficacy and Safety



Drug discovery power for antiviral drugs + modalities

- **Changes in external environment surrounding COVID-19 drug development**
 - While the development of therapeutic drugs is progressing using various modalities, the number of discontinuations / EUA cancellations is also increasing
 - > Antibody drugs, plasma fractionated drugs, etc.
 - The emergence of "a truly effective and safe drug" is still awaited
- **Shionogi's action**
 - Conducting drug discovery at top speed using various modalities
 - > Selecting promising compounds from multiple approaches
 - **With a view to addressing mutant virus, promising oral compounds from small molecule drug discovery were selected**

A "therapeutic drug" is essential to ending the pandemic
Start clinical trials during the first half

Responding to exacerbation risk using existing assets

- **BioAge began Ph2 trials of asapiprant**
 - Asapiprant: discovered by Shionogi as S-555739
 - Prostaglandin D₂ DP1 receptor antagonist developed as allergic rhinitis drug; proven to be well tolerated and safe
 - **Improvement of mortality rates in SARS-CoV-2-infected aged mice**
 - Ph2 trials in the US, Brazil, and Argentina in elderly patients are ongoing
 - > Top line data expected to be obtained in 2021
 - Decision on domestic development based on overseas clinical trial results

Promptly provide a solution to eliminate patient anxiety along with therapeutic drugs*

Identify Patients at Risk of Exacerbation



Diagnostic markers that can predict exacerbation

- **HISCL[®] TARC^{*} reagent**
 - It is difficult to ascertain patients who have the risk of exacerbation in the early stages of COVID-19, and **the risk of healthcare system collapse due to increased patient hospitalization and isolation is a concern for society**
 - > Measurement of serum TARC levels in COVID-19-positive patients **enables focus on patients who are at risk of exacerbation, thus optimizing use of medical resources**
 - > Highly specific markers that can be assessed even in patients with underlying disease

Filed application for approval for additional indication for use in prediction of risk of exacerbation (April 16, 2021)

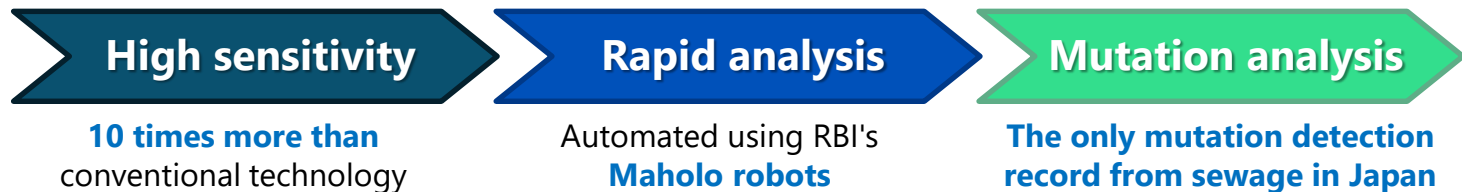


Contributing to reduce the risk of collapse/overwhelming of medical system

Establishment of analysis system for SARS-CoV-2 in sewage

- Periodic monitoring of SARS-CoV-2 accumulation in sewage treatment plants and facility sewage makes it possible to obtain epidemiological information at the population level
- Collaboration with Hokkaido University, RBI*, and iLAC **to facilitate assessment of how COVID-19 is spreading and when an outbreak starts and will end, as well as early detection of trends in the proliferation and emergence of mutant virus**
- Started monitoring viral loads and genetic analysis in Osaka Prefecture since April
- **Service set to be launched in mid-June**

Sewage monitoring conducted by Shionogi



Expected to contribute to both infection control and resumption of economic activities

To Avoid Continual Social Anxiety Caused by Infectious Diseases



Strengthen preparations for the next pandemic

- Accurate prediction of pandemics is difficult (COVID-19, flu, etc.)
- While the spread of COVID-19 has certainly raised public awareness of infectious diseases, crisis management for the next pandemic remains insufficient



Infectious disease control is an important issue closely related to national security

- Industry, government, and academia can work together to strengthen preparedness
- A framework is needed to prepare for emergencies arising from infectious diseases

Preparation of Shionogi

- Strengthening our actions in the infectious disease field as a core therapeutic area, and developing a business that offers total care
- Policy recommendations and contributions to global health through industry activities
- **Stable operation of infectious disease business**

Business Plan in FY2021



In addition to the COVID-19-related business, which is expected to undergo rapid evolution*, 2021 will be a year with abundant new business opportunities

Expand infectious disease-related business

- **Providing COVID-19 related products and services:**
Changes due to development, policies, etc.
- **Changes in each country's response to prepare for emergencies such as flu and AMR, etc.**
 - Possibility of expansion of stockpiling, subscription model, etc.
 - Creation of new healthcare-related business

Establish a new business model for infectious diseases

Acquire new growth drivers

- Product introduction, M&A
- Aggressive investment for early expansion of new business
- Maximization of assets and franchises, consideration of partnering

**Expansion of new business
Creating new revenue opportunities**

Start by strengthening the base business, and grow sales and profits by creating and expanding new businesses

Financial Forecasts



(Unit: B yen)

	FY2021 Forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	290.0	135.0	297.2	(2.4)	(7.2)
Operating profit	90.0	38.5	117.4	(23.4)	(27.4)
Core operating profit*	90.0	38.5	94.0	(4.2)	(4.0)
Profit before tax	115.0	48.5	143.0	(19.6)	(28.0)
Profit attributable to owners of parent	100.0	49.5	111.9	(10.6)	(11.9)

- Decrease in sales and operating profit without new business opportunities included
- Reflect refund due to finally prevailing in court regarding cancellation of correction disposition from National Taxation Bureau**

Changes in earnings forecasts due to business opportunities will be promptly announced

Exchange Rate (average)	FY2021 forecast	FY2020 results
USD (\$) –JPY(¥)	105.00	106.11
GBP (£) –JPY(¥)	145.00	138.75
EUR (€) –JPY(¥)	128.00	123.76

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

** Released on May 6, 2021 (refund of about 13.3 billion yen)

Statement of Profit or Loss Forecast



(Unit: B yen)

	FY2021 forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Revenue	290.0	135.0	297.2	(2.4)	(7.2)
Cost of sales	19.8 57.5	18.5 25.0	17.7 52.5	9.5	5.0
Gross profit	232.5	110.0	244.7	(5.0)	(12.2)
Selling general & administrative expenses	30.7 89.0	32.6 44.0	32.0 95.1	(6.4)	(6.1)
R&D expenses	17.9 52.0	18.5 25.0	18.3 54.2	(4.1)	(2.2)
Other income & expenses	(1.5)	(2.5)	22.1	—	(23.6)
Operating profit	31.0 90.0	28.5 38.5	39.5 117.4	(23.4)	(27.4)
Core operating profit*	31.0 90.0	28.5 38.5	31.6 94.0	(4.2)	(4.0)
Finance income & costs	25.0	10.0	25.6	(2.3)	(0.6)
Profit before tax	39.7 115.0	35.9 48.5	48.1 143.0	(19.6)	(28.0)
Profit attributable to owners of parent	100.0	49.5	111.9	(10.6)	(11.9)

Revenue Forecast by Segment



(Unit: B yen)

	FY2021 forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Domestic Prescription drugs*	94.4	46.1	94.7	(0.3)	(0.3)
Overseas subsidiaries/export	31.1	12.2	24.6	26.2	6.5
Shionogi Inc.	8.4	4.2	7.5	12.5	0.9
Ping An-Shionogi** /C&O	14.3	3.9	10.1	42.0	4.2
Contract manufacturing	17.8	7.4	19.7	(9.7)	(1.9)
OTC and quasi-drug	15.4	6.9	11.7	31.8	3.7
Royalty income	129.8	61.7	144.6	(10.3)	(14.8)
HIV franchise	125.2	60.8	123.4	1.5	1.9
Crestor®	1.1	—	16.6	(93.7)	(15.5)
Others	3.5	0.9	4.7	(25.4)	(1.2)
Others	1.4	0.7	1.8	(18.2)	(0.3)
Total	290.0	135.0	297.2	(2.4)	(7.2)

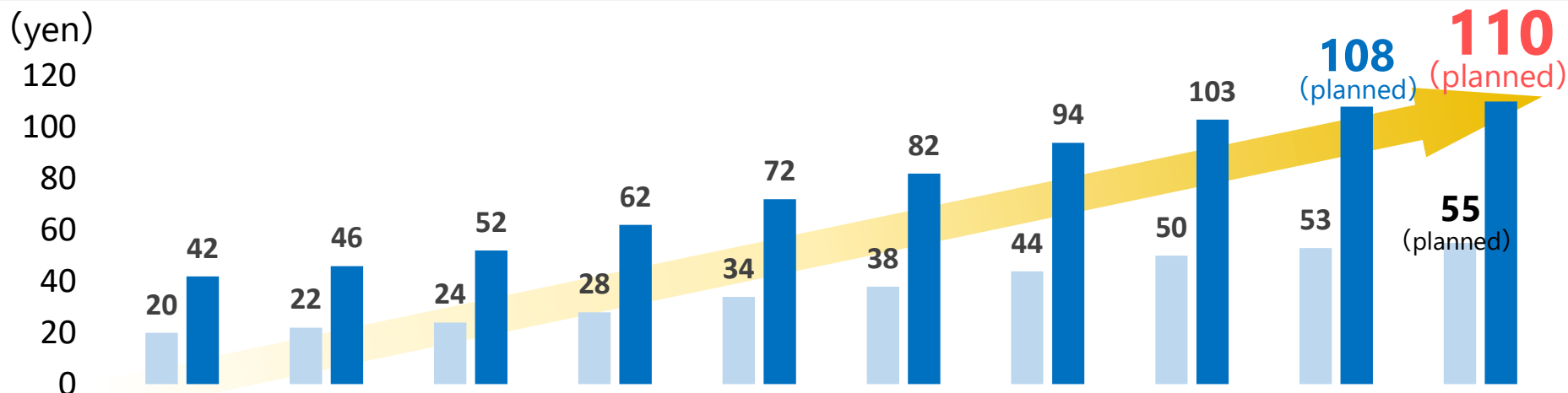
3. Shareholder Return

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 in FY2021 for the tenth consecutive year**



FY		12	13	14	15	16	17	18	19	20	21
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	
	Cancellation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1 (planned)	Over 4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	Over 11.5 (expected)

Converted from JGAAP to IFRS after FY2019

As a Company Needed by Society



— Shionogi's commitment in FY2021 —

As a leading company in the infectious disease field

Shionogi will work intensively to counter the COVID-19 pandemic as our highest priority

Material issues to create new value for customers and society

Protect people worldwide from the threat of infectious diseases

- Develop infectious-disease-related products and accurately convey associated information
- Address AMR/viral infectious diseases (influenza, corona, etc.)
- Address three major infectious diseases (HIV, TB, malaria)



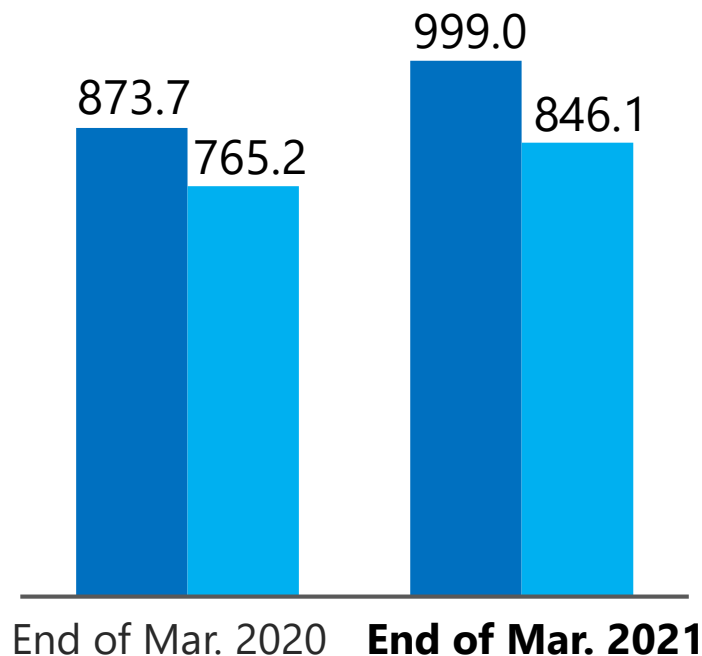
Appendix

Financial Position (Consolidated, IFRS)



■ Total Assets ■ Equity attributable to owners of parent

(Unit: B yen)



Unit: B yen		End of Mar. 2020	End of Mar. 2021	Change
Total Assets	Non-current Assets	357.7	442.8	85.1
	Current Assets	516.0	556.2	40.2
Equity attributable to owners of parent		765.2	846.1	81.0
Total Liabilities	Non-current Liabilities	27.4	34.3	6.9
	Current Liabilities	81.1	100.2	19.1

	End of Mar. 2020	End of Mar. 2021
Ratio of equity attributable to owners of parent to total assets	87.6%	84.7%

Impact of COVID-19 on 3Q FY2020 and Our Response

- **Supply chain**

- Continue to procure overseas imported raw materials ahead of schedule and secure inventories, and increased monitoring of manufacturing of active pharmaceutical ingredients (APIs) and products by suppliers and CMOs ⇒ Achieve stable supply for the full year
- Raw materials ordered ahead of schedule are delivered in 4Q, reducing risk for stable supply

- **Promotion**

- Domestic: Opportunities to face-to-face meetings with physicians at large hospitals are reduced by about 50% compared to before COVID-19
- Domestic: Providing information virtually, in an efficient manner, through web-conferences and e-details, in combination with face-to-face or online meetings, depending upon the needs of each medical institution
- Overseas: Providing information and promoting antimicrobial stewardship by virtual communications on cefiderocol

- **R&D**

- Resources allocated for the realization of total care of COVID-19 with therapeutic drugs, vaccines, and diagnostics
- Core 8 projects* progressed almost as planned without major delays** even in COVID-19 situation
- CMC: Completed the first phase of vaccine production as planned and moved to the second phase

FY2020 Pipeline Target Milestones



Phase	Pipeline	Indication	Milestone	✓ : achieved
Submission~ Approval	Fetroja® (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval ✓	
	Fetroja® (cefiderocol)	Aerobic Gram-negative bacterial infection*	EU: Approval ✓	
	Xofluza® granules	Influenza virus infection (Pediatric, <20 kg)	Japan: Supplemental approval	
	Xofluza®	Influenza virus infection (Prophylaxis)	Japan: Supplemental approval ✓	
	Oxycontin® TR	Analgesia in chronic pain	Japan: Supplemental approval ✓	
	Cymbalta®	Depression (Pediatric)	Japan: Submission	Discontinued
Phase 1~3	S-637880	Neuropathic pain	Japan: Completion of Phase MAD ✓	
	S-637880**	Neuropathic low back pain**	Japan: Initiation of Phase 2 (PoC) ✓	
	S-648414	HIV infection	US: Initiation of Phase 2 (PoC)	
	S-770108	Idiopathic pulmonary fibrosis	UK: Initiation of lung deposition study ✓	
	S-540956	HIV infection, cancer	US: Initiation of Phase 1	
	S-874713	Psycho-neurological disease	Japan: Initiation of Phase 1	
	BPN14770	Alzheimer's disease	Japan: Initiation of Phase 1 ✓	
	S-723595	NASH	Japan: Initiation of Phase 1 ✓	

* Patients 18 years of age or older who have limited or no alternative treatment options

** Due to a change in the development policy, S-637880 alone was developed for neurological low back pain from a clinical trial that evaluates S-637880 and S-600918 within the same study

Pipeline: Infectious Disease



as of May 10, 2021



Out license

Advanced

S-555739

Treatment by suppressing aggravation of COVID-19

cabotegravir LAP
Prophylaxis of HIV infection

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

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

Xofluza®
Influenza virus infection
(Transmission)

Stage change (Changes from Feb. 1, 2021)

S-555739 (Treatment by suppressing aggravation of COVID-19):
Phase 2 start (US)
Xofluza® (Influenza virus infection (High-dose for children):
Discontinued (Japan)
Xofluza® (Influenza virus infection (Severe hospitalised)):
Discontinued (Global)



SHIONOGI

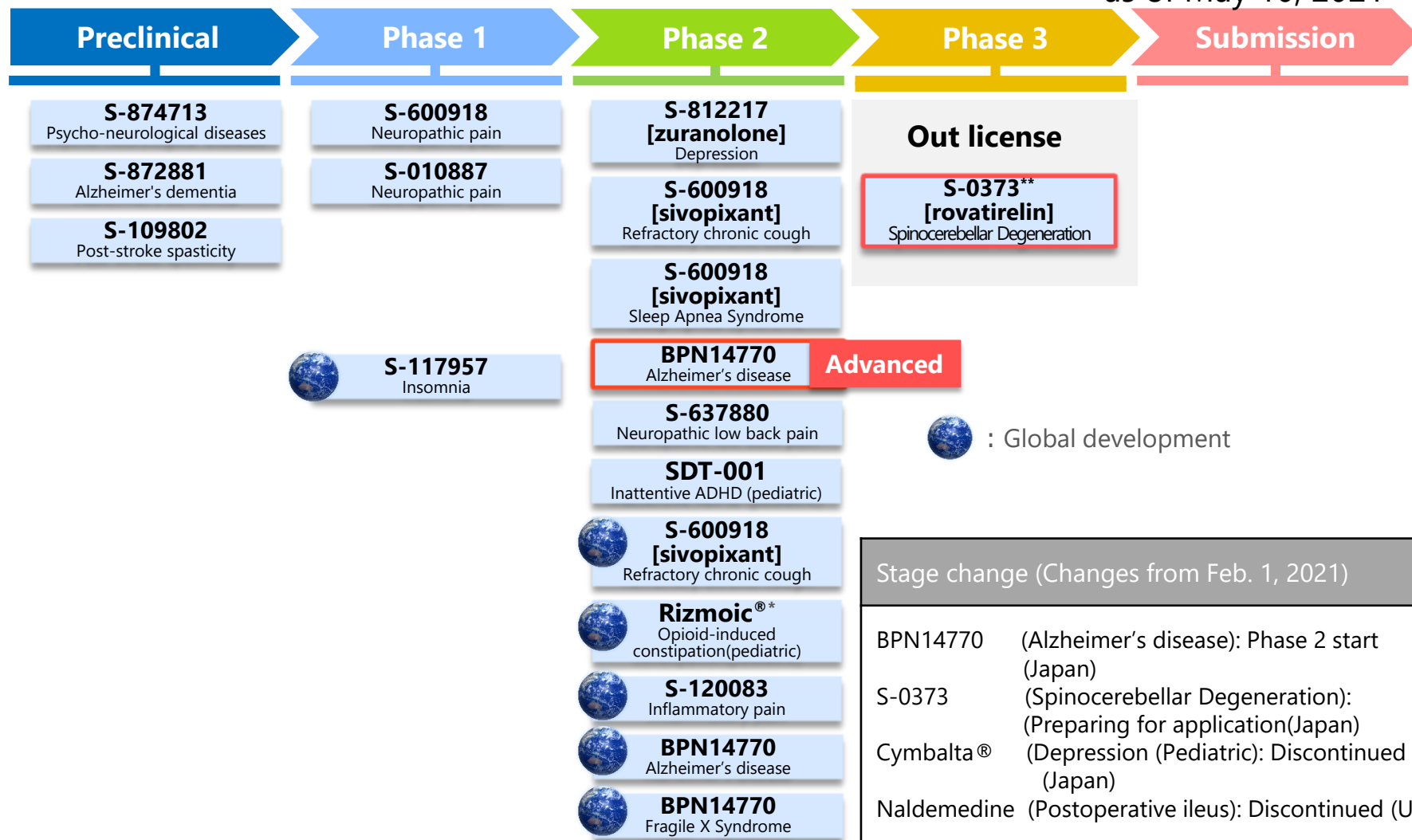


: Progress from Feb 1, 2021 to May 10, 2021

Pipeline: Psycho-neurological Disease



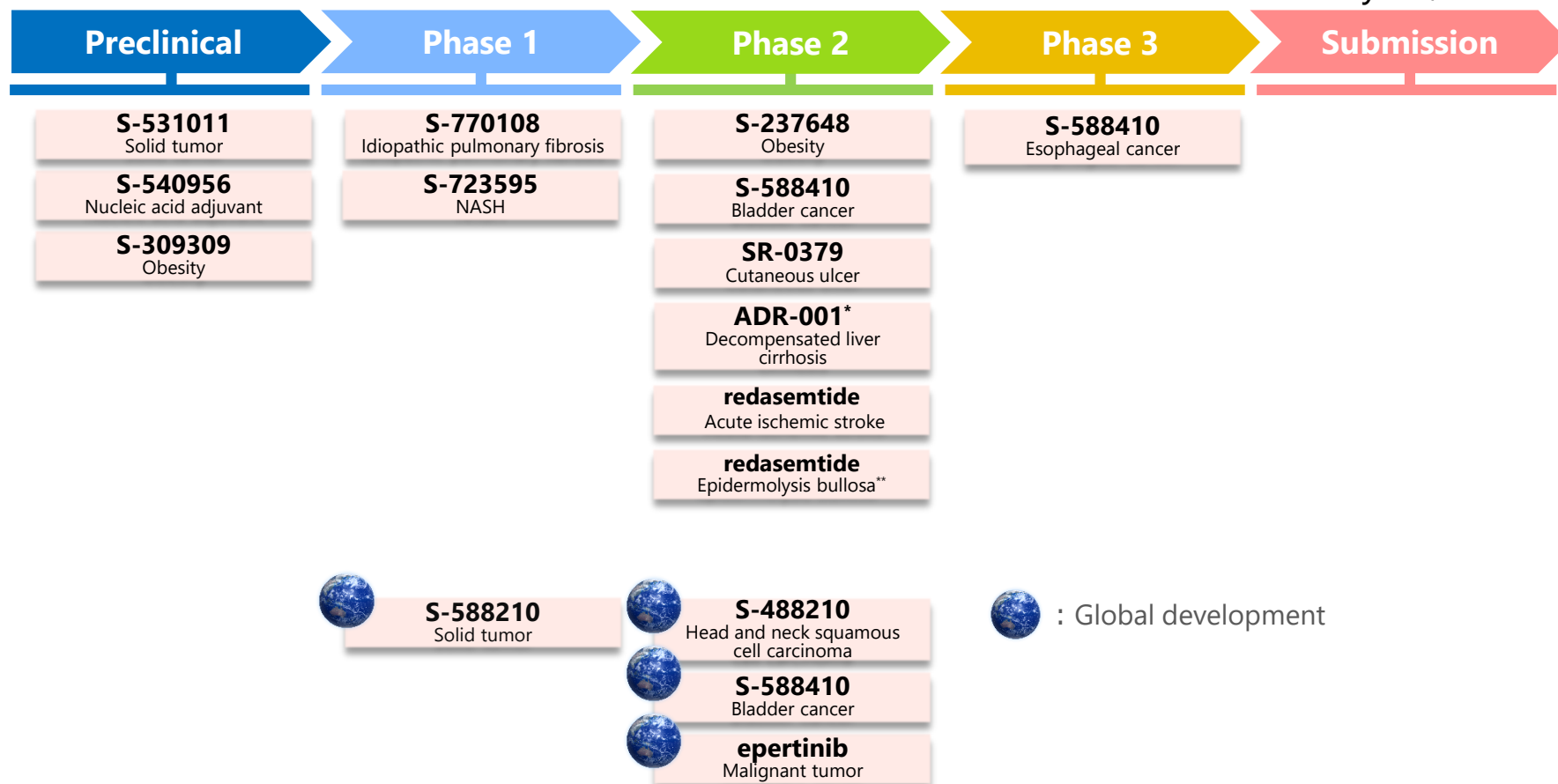
as of May 10, 2021



Pipeline: New Growth Area



as of May 10, 2021



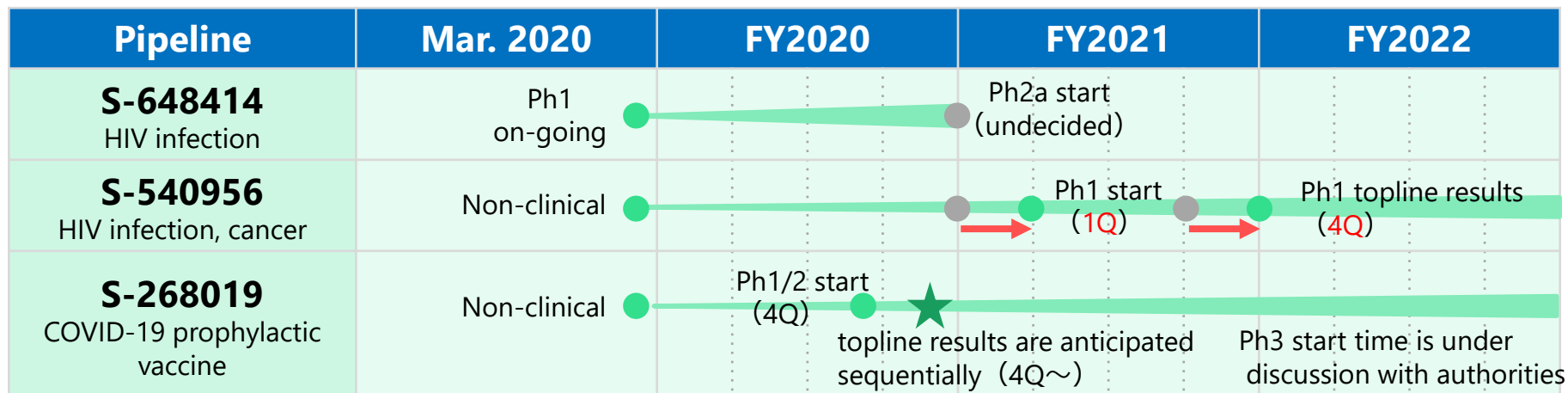
Stage change (Changes from Feb. 1, 2021)

S-237648 (Obesity): Discontinued (US) ***
S-707106 (Type 2 diabetes): Discontinued (US)

Key Events for Major Pipeline Compounds



as of May 10, 2021

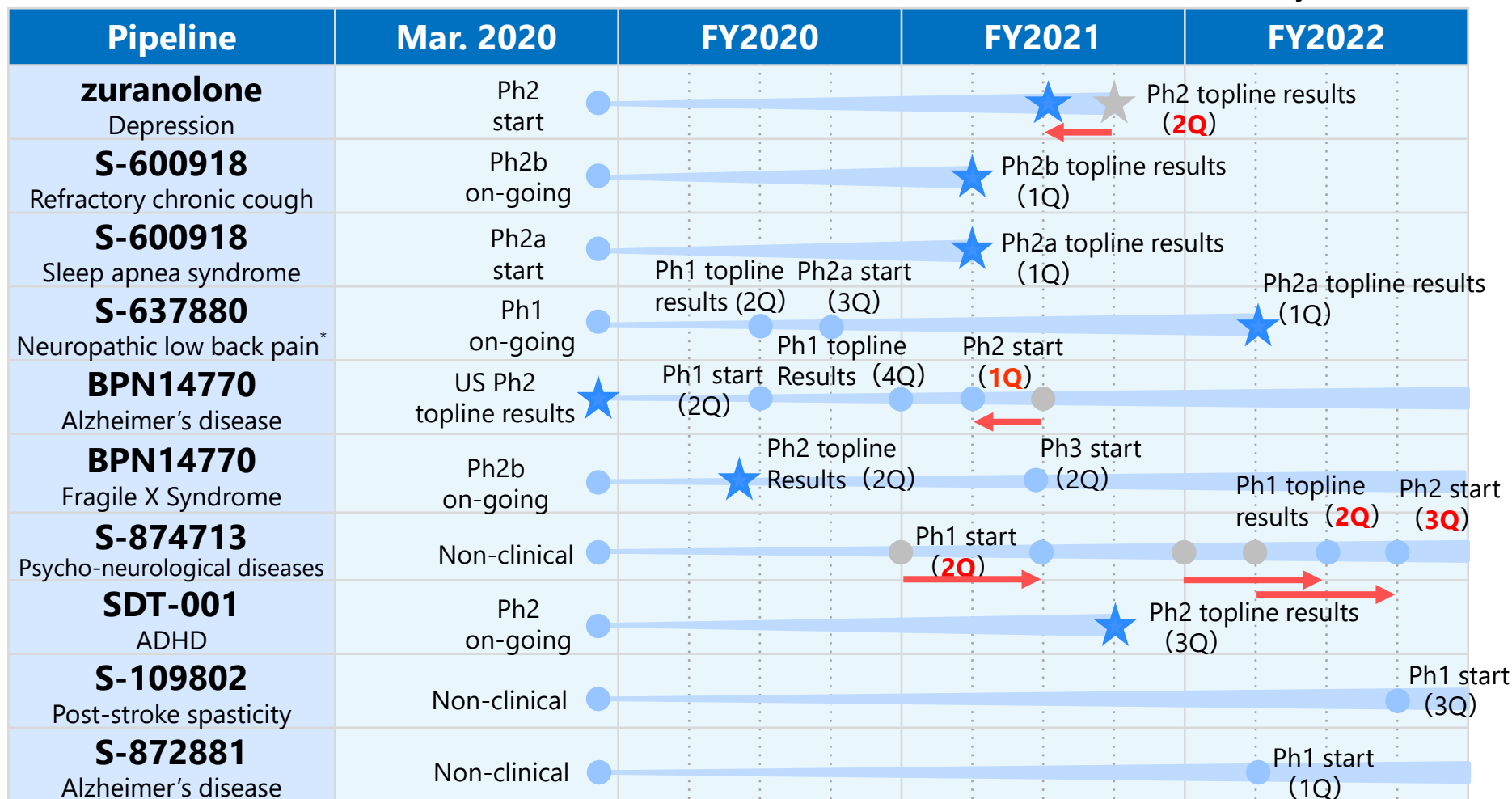


★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and method under consideration)

Key Events for Major Pipeline Compounds



as of May 10, 2021

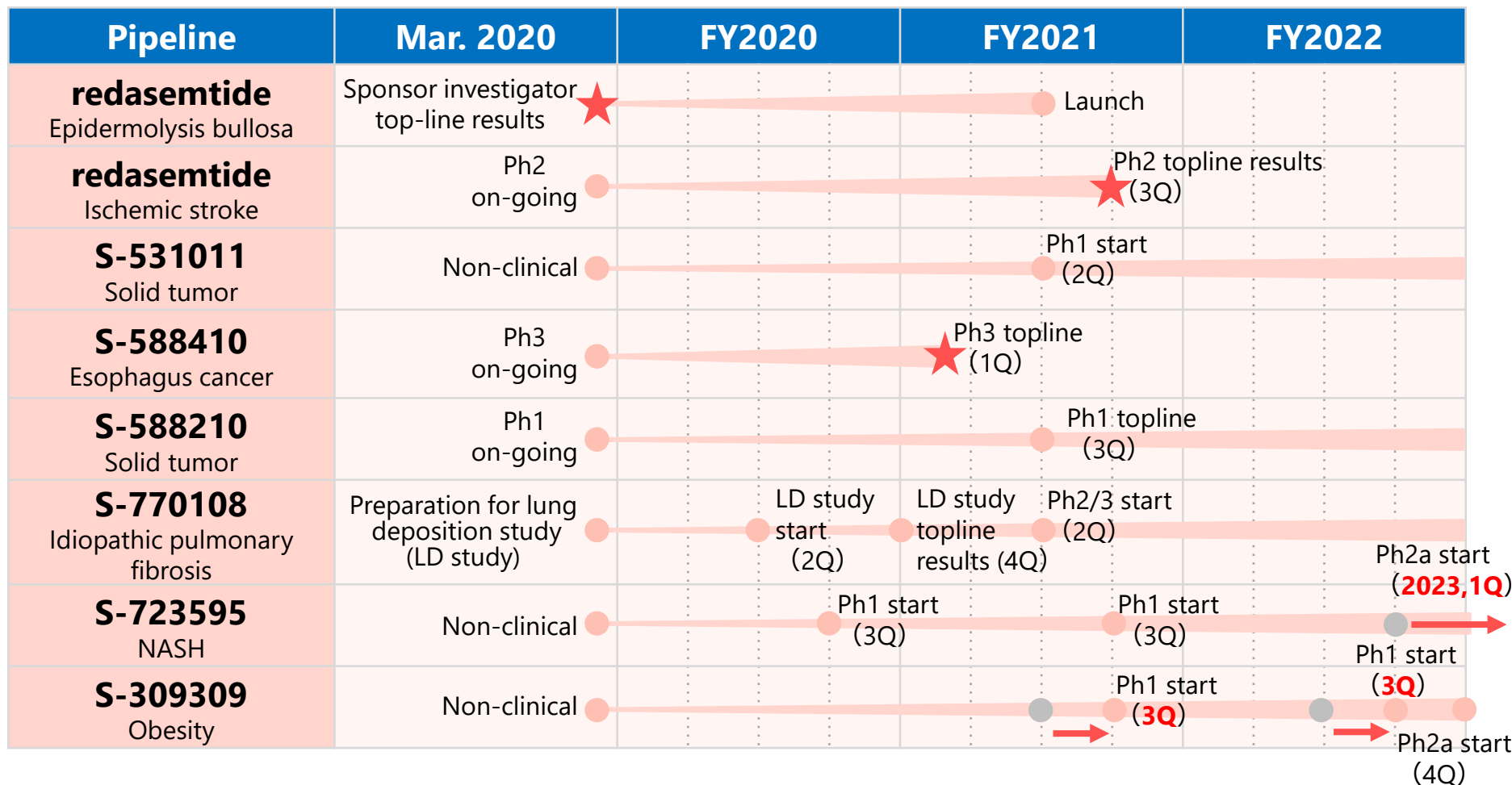


★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and method under consideration)

Key Events for Major Pipeline Compounds



as of May 10, 2021



★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and method under consideration)

Revenue Forecasts for Prescription Drugs in Japan



(Unit: B yen)

	FY2021 forecasts		FY2020	Y on Y	
	Full year	1H	Results	Change (%)	Change (B yen)
Cymbalta[®]	15.1	10.0	26.5	(42.9)	(11.3)
Intuniv[®]	18.2	8.5	13.1	39.5	5.2
Vyvanse[®]	1.0	0.4	0.3	288.1	0.8
Infectious disease drugs	17.0	4.8	9.8	74.4	7.3
Influenza franchise	7.9	0.2	0.3	2,957.0	7.6
OxyContin[®] franchise	5.0	2.6	5.3	(6.2)	(0.3)
Symproic[®]	3.1	1.3	2.3	37.4	0.8
Actair[®]	0.4	0.2	0.3	12.1	0.0
Mulpleta[®]	0.1	0.1	0.1	18.3	0.0
Pirespa[®]	3.5	1.8	5.1	(31.8)	(1.6)
Others	30.9	16.4	32.0	(3.5)	(1.1)
Crestor [®]	6.5	3.8	6.7	(2.5)	(0.2)
Irbetan [®] franchise	3.1	1.7	3.3	(7.7)	(0.3)
Prescription drugs	94.4	46.1	94.7	(0.3)	(0.3)

<Products included in infectious disease drugs>

• Xofluza[®]
• Rapiacta[®]
• Brightpoc[®] Flu・Neo

• FINIBAX[®]
• Flumarin[®]
• Flomox[®]

• Ceftem[®]
• Shiomarin[®]
• ISODINE[®]

• Baktar[®]
• Flagyl[®]
• Fluconazole

Rapid and highly sensitive antigen test

- **LumiraDx SARS-CoV-2 Ag Test Strip***
 - An antigen test that overcomes the issues of **speed** in PCR test and **sensitivity** in antigen test
 - > Diagnostic results similar to those from PCR can be **easily obtained in 12 minutes from a drop of nasopharyngeal/nasal swab fluid**
 - > Preparing to **start sales by the end of May 2021**
 - > Widely applied to other infectious diseases with the same device

Rapid diagnosis of multiple samples

- **SATIC***
 - **Technology that can visually disclose the infection in about 25 minutes using saliva samples**
 - > Ongoing product development to provide genetic diagnostic kits capable of highly sensitive and rapid diagnosis
 - > Under discussion with collaborative research partner on a method that can test with multiple samples

FY2021 action

- **Strengthen sales alliances with online medical platforms**
 - **Expand product range**
 - > Increased range of C&O products and Shionogi Healthcare's products
 - > Introducing products (GE, OTC) suited to online prescription
 - **Expand sales channels**
 - > Develop new offline and online sales networks
 - **Maximize value through use of RWD***
 - > Provide wearable devices to patients when certain products are prescribed, adding post-prescription follow-up function to online medical care
 - = Along with supporting compliance and proper use, collect data for AI drug discovery by monitoring drug efficacy.

New drug development

- **Cefiderocol, naldemedine**
 - A pre-NDA meeting will be held in 1H of FY2021 with the aim of filing a Chinese NDA application within the year.
 - Contribute to profits from FY2022

Actions for Medium to long term increase in corporate value

AI drug discovery research



- **Use AI technology to search for candidate compounds that broadly act on the target genes in specific CNS diseases**
 - **Narrowed candidates down** from 500,000 or more to **about 100**
 - Aiming to start non-clinical trials by end of FY2021

Smart factories





- **Apply AI technology to pharmaceutical manufacturing to automate manufacturing and quality management**
 - Steady progress toward implementation
 - **Completed characterization of risk of deviation in weighing process**

Accelerate contribution to revenue through use of online medical treatment platforms, creation of new drugs and realization of HaaS

Building a foundation for new value creation

Pursued advanced decision making and cost structure reform

Education and training for all managers: Project KANAME

- 
- 
- 1) Understanding of new medium-term management plan
 - 2) Approval process
 - 3) Management and personnel evaluation
 - 4) Labor management

Advanced decision making based on management and business strategies

- Increase understanding of strategy throughout the managerial organization
- Decision-making based on assessment of business risk, at the proper level

Developed human resources as a source of competitive advantage

- Improve motivation and collaboration
- Develop human resources who can take on challenges in the realization of HaaS



Improvement of concrete aspects

- Establishment of a system that ensures transparency and traceability in decision making.
- Tight linkage with management accounting

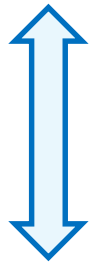
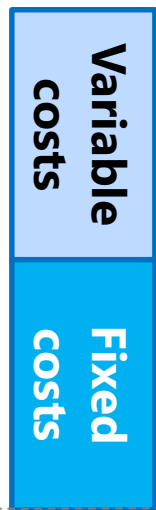
Visualize and deeply consider resource utilization

Software and hardware reforms implemented in FY2020



For current businesses

Focus that ensures a high rate of return



Ability to adjust and manage priorities within the budget depending on the progress of the business

Capability to add future businesses

Invest to generate a high rate of return



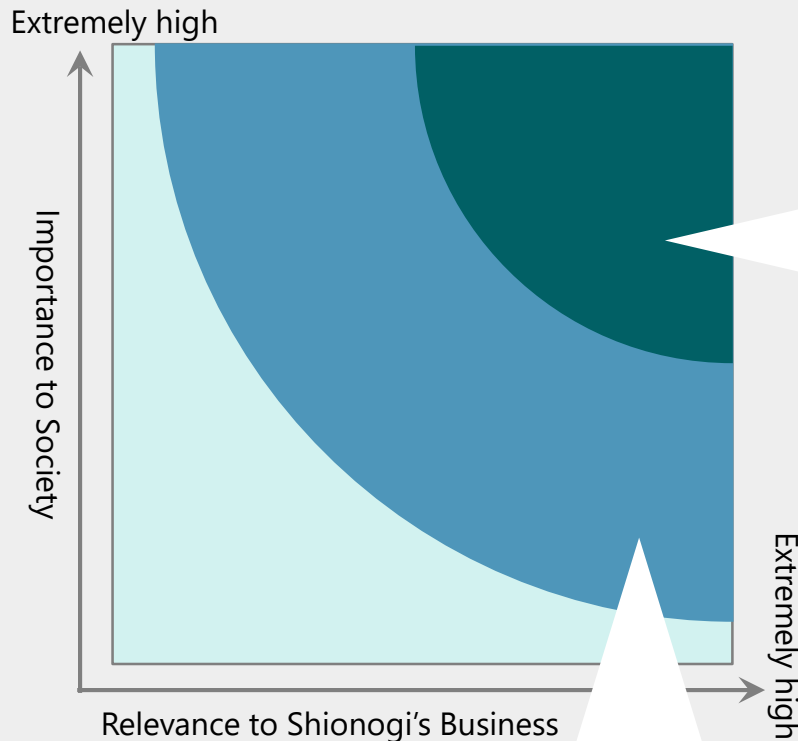
Ability to turn fixed costs into variable costs and create new highly-profitable businesses

Through cost transparency and advanced decision-making, make it possible to release investment capacity for new growth while reducing costs

Material Issues to Be Tackled by Shionogi



Material issues determined in light of external/internal changes in environment



- Improve access to healthcare
- Strengthen corporate governance
- Secure human resources to support growth
- Protect the environment
- Ensure compliance
- Supply socially responsible products and services
- Reinforce supply chain management
- Respect human rights

- **Protect people worldwide from the threat of infectious diseases**
 - Develop infectious-disease-related products and distribute accurate information about them
 - Big three infectious diseases (HIV, TB, malaria)
 - AMR/viral infectious diseases (influenza, corona, etc.)
- **Improve social productivity and extend healthy lifespans**
 - Contribute to raising social productivity (chronic back pain, depression, etc.)
 - Contribute to the ultra-aged society (dementia, cancer, etc.)
- **Contribute to sustainable social security**
 - Provide medical care optimized for the individual
 - Deliver at suitable prices that are commensurate with value

SDGs that Shionogi can help to achieve



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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