



1st Half of Fiscal 2020 Financial Results

November 2, 2020

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President and CEO



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1. Overview of 1st Half FY2020 Financial Results

Business Impact of COVID-19



Impact of COVID-19 on 1st Half FY2020 and Our Response

- **Supply chain**

- No impact on procurement of raw ingredients etc., production, or inventory – no hindrance to stable supply
- Accelerated production of some products and secured inventory of materials imported from overseas

- **Promotion**

- Patient visits for medical institutions in Japan are returning to approximately 70% of pre-COVID-19 levels, except for major hospitals.
- Providing information virtually efficiently through web-conferences and e-details, in combination with face-to-face or online meetings, depending upon the needs of each medical institution
- Continuing to train sales reps for comprehensive understanding of disease, in collaboration with the Integrated Disease Care Division

- **R&D**

- Focus resources on COVID-19 related projects
- No significant impact on the development timelines for 8 core projects* and other projects in the 2nd quarter**

Financial Results (Consolidated)



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Revenue	323.5	155.6	148.5	95.4	163.6	(9.3)	(15.2)
Operating profit	110.3	53.8	55.3	102.7	63.2	(12.5)	(7.9)
Core operating profit**	110.3	53.8	55.8	103.6	63.5	(12.1)	(7.7)
Profit before tax	136.3	61.6	67.2	109.0	70.7	(4.9)	(3.5)
Profit attributable to owners of parent	103.6	44.9	49.4	110.0	54.4	(9.2)	(5.0)

- Revenue target was not achieved due to contraction of the pharmaceutical market, especially in the infectious disease areas, under the budget plan of decreased sales and profits
- Achieved all profit targets by managing costs in this changing business environment while maintaining investment in research and development

Exchange Rate (average)	FY2020 Forecasts	FY2020 Apr.-Sep. Results
USD (\$) – JPY (¥)	107	106.93
GBP (£) – JPY (¥)	130	135.42
EUR (€) – JPY (¥)	120	121.34

* Converted from JGAAP to IFRS

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



SHIONOGI

Statement of Profit and Loss (Consolidated)



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Revenue	323.5	155.6	148.5	95.4	163.6	(9.3)	(15.2)
Cost of sales	17.2 55.7	16.5 25.7	15.4 22.9	89.0	16.9 27.7	(17.5)	(4.8)
Gross profit	267.8	129.9	125.6	96.7	135.9	(7.6)	(10.3)
Selling general & administrative expenses	32.1 103.7	33.2 51.6	30.2 44.8	86.7	29.5 48.3	(7.2)	(3.5)
R&D expenses	15.5 50.2	14.8 23.0	16.7 24.9	107.8	14.3 23.3	6.5	1.5
Other income	0.5	0.3	0.2	93.3	0.2	0.2	0.0
Other expenses	4.0	1.6	0.9	55.5	1.4	(34.6)	(0.5)
Operating profit	34.1 110.3	34.6 53.8	37.3 55.3	102.7	38.6 63.2	(12.5)	(7.9)
Core operating profit	34.1 110.3	34.6 53.8	37.6 55.8	103.6	38.8 63.5	(12.1)	(7.7)
Finance income	27.5	8.4	12.8	152.3	9.7	31.8	3.1
Finance costs	1.6	0.6	0.9	151.3	2.3	(59.0)	(1.3)
Profit before tax	42.1 136.3	39.6 61.6	45.3 67.2	109.0	43.2 70.7	(4.9)	(3.5)
Profit attributable to owners of parent	103.6	44.9	49.4	110.0	54.4	(9.2)	(5.0)

Revenue by Segment



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts*		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Domestic Prescription drugs	123.9	53.1	47.2	88.8	51.5	(8.3)	(4.3)
Overseas subsidiaries/export	24.0	11.3	11.0	97.7	17.5	(37.3)	(6.5)
Shionogi Inc.	5.1	2.6	3.3	128.9	6.8	(50.9)	(3.5)
C&O	11.9	5.7	4.2	74.8	7.2	(40.6)	(2.9)
Contract manufacturing	15.4	7.9	6.7	84.6	10.1	(33.7)	(3.4)
OTC and quasi-drug	10.4	4.9	5.5	112.8	4.4	24.5	1.1
Royalty income	148.3	77.8	77.3	99.4	79.1	(2.2)	(1.7)
HIV franchise	126.3	64.2	63.9	99.6	64.9	(1.6)	(1.0)
Crestor®	16.9	11.1	11.1	100.0	11.3	(1.2)	(0.1)
Others	5.2	2.5	2.3	92.2	2.8	(20.7)	(0.6)
Others	1.3	0.7	0.8	121.6	1.1	(27.1)	(0.3)
Total	323.5	155.6	148.5	95.4	163.6	(9.3)	(15.2)

Revenue of Prescription Drugs in Japan



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results*	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta [®]	28.6	13.9	13.5	96.9	12.9	4.7	0.6
Intuniv [®]	16.7	6.8	6.0	88.3	4.5	35.1	1.6
Vyvanse ^{®**}	0.8	0.2	0.1	34.0	-	-	0.1
Infectious disease drugs	26.5	7.1	4.9	68.5	7.3	(33.5)	(2.5)
OxyContin [®] franchise	5.6	2.9	2.8	95.5	3.1	(10.0)	(0.3)
Symproic [®]	2.9	1.3	1.1	81.4	1.1	0.8	0.0
Actair [®]	0.4	0.2	0.1	90.6	0.1	22.4	0.0
Mulpleta [®]	0.1	0.1	0.1	90.7	0.1	(23.0)	(0.0)
Pirespa [®]	4.9	2.9	2.8	98.5	3.4	(17.6)	(0.6)
Others	37.5	17.7	15.8	89.4	19.0	(16.8)	(3.2)
Crestor [®]	8.3	4.2	3.7	88.4	4.4	(16.9)	(0.7)
Irbetan [®] franchise	3.7	1.8	1.7	94.2	2.2	(22.1)	(0.5)
Prescription drugs	123.9	53.1	47.2	88.8	51.5	(8.3)	(4.3)

<Products included in infectious disease drugs>

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

Summary of 1st Half -1-



Year-on-Year Comparison

- **Revenue (-15.2 B yen [-9.3%]** reference: -9.4 B yen at 1Q)
 - Japan
 - > **Sales growth of Cymbalta® and Intuniv®**
 - > Impact of price revision (long-listed products in “Infectious diseases drugs” and “Others”)
 - Overseas :
 - > US: One-time payments received from BDSI for Symproic® in FY2019
 - > China: Decrease in sales of rabeprazole in the hospital market
 - Contract manufacturing
 - > Temporal reduction of dolutegravir API supply, due to manufacturing process improvements (already included in the original forecast)
 - > Decreased Xofluza® exports due to conservative epidemic forecast for this flu season
 - Royalty revenue
 - > Exchange rates impact on royalty income from HIV franchise
- **Selling general & administrative expenses (-3.5 B yen [-7.2%]** reference: -2.2 B yen at 1Q)
 - Decrease in costs due to less field activity in COVID-19 environment (reduced travel expenses, car expenses)
 - Investment for telework environment
- **R&D expenses (1.5 B yen [6.5%]** reference: 0.5 B yen at 1Q)
 - Ensuring and accelerating progress of 8 core projects including S-600918 and S-005151, and full-blown commitment to COVID-19 related projects

Summary of 1st Half -2-



1st Half forecast comparison

- **Revenue (-7.1 B yen)**
 - Japan:
 - > ADHD family: decreased market penetration opportunity due to slow recovery from COVID-19 reduction of physician visits by pediatric patients
 - > Infectious disease drugs: decreased prescriptions due to reduction in physician visits and in non-emergency surgery in many clinical departments
 - Overseas:
 - > U.S.: **Steady progress of cefiderocol (Fetroja®)**
 - Contract manufacturing : Adjustment of Xofluza® export to reflect low epidemic projections, while dolutegravir manufacturing exceeded expectations
 - OTC and quasi-drug: Sales increase of infectious disease-related products
 - Royalty revenue: **Achieved as forecasted**
- **Selling general & administrative expenses (-6.9 B yen)**
 - Cost reduction due to reduced sales activities and switching to virtual promotion with digital information
 - Decrease in cost due to reduced sales of rabeprazole in China
- **R&D expenses (1.8 B yen)**
 - Further acceleration of COVID-19-related projects
 - Investment to advance the development of core 8 projects at top speed under the COVID-19 expanding environment
 - > Addition of participation centers for clinical trials, flexible expansion of areas/countries for recruiting patients, etc.

Summary of 1st Half



Market contraction and unachieved sales targets

- Although progress was made in implementing virtual detailing activities, especially for Cymbalta[®], it was not possible to compensate for the contractions in the infectious diseases and pediatrics areas
- Steady progress of US and OTC businesses

Resource management

- Strict resource management reflecting current realities while still reliably supplying our products and product information, even in an unstable environment
- Active investment in R&D for medium to long term growth

Achieved profit targets through cost management while actively investing in R&D even though revenue did not reach the target

2. FY2020 Financial Forecasts

Basis for revision of forecast

The pharmaceutical market will continue to be unstable due to prolonged effect of pandemic and sustained societal anxiety, although patients are gradually coming back to doctors



Improving Productivity

- Providing information from both the "product axis" and "disease axis" perspectives
- Company-wide work style reforms
- Improving business processes for efficiency and transparency
- IT investments for productivity and security

Aggressive R&D Investment

- Acceleration of COVID-19-related projects
- Progress of core 8 projects
- Vaccine business

Investment in Multiple Deals

- Joint venture business with Ping An group
- Nagase Medicals
- Further deals for medium to long term growth

While maintain growth-driving investments to achieve STS2030 goals, the profit targets for FY2020 are secure

Revision of earnings forecast (Announced on October 30, 2020)



(Unit: B yen)

	FY2020 Forecasts Full year			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	318.1	(5.4)	333.4	(4.6)	(15.3)
Operating profit	110.3	133.2	22.9	130.6	2.0	2.6
Core operating profit**	110.3	108.5	(1.8)	127.4	(14.8)	(18.8)
Profit before tax	136.3	159.6	23.3	158.5	0.7	1.1
Profit attributable to owners of parent	103.6	119.7	16.1	122.2	(2.0)	(2.5)

- The revenue of initial forecast is expected not to be achieved, considering the 1st half result and the market environment
- A gain on exchange of Shibuya Building*** will give **significant positive profit impact**
 - Resulting in similar profit levels to previous year
 - No change in profit forecasts when this factor is removed*****

Exchange Rate (average)	FY2020 Forecasts (May 11)	FY2020 Forecasts (Oct. 30)	FY2020 Apr.-Sep. results
USD (\$) – JPY (¥)	107	107	106.93
GBP (£) – JPY (¥)	130	135	135.42
EUR (€) – JPY (¥)	120	120	121.34

Revision of earnings forecast

Statement of Profit and Loss (Consolidated)



(Unit: B yen)

	FY2020 Forecasts			FY2020 2H Forecasts			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	318.1	(5.4)	167.9	169.6	1.8	333.4	(4.6)	(15.3)
Cost of sales	17.2 55.7	17.3 55.1	(0.6)	17.9 30.0	19.0 32.2	2.2	17.0 56.8	(3.0)	(1.7)
Gross profit	267.8	263.0	(4.7)	137.9	137.4	(0.5)	276.6	(4.9)	(13.6)
Selling general & administrative expenses	32.1 103.7	31.5 100.2	(3.5)	31.0 52.1	32.7 55.4	3.4	29.5 98.4	1.9	1.9
R&D expenses	15.5 50.2	16.4 52.0	1.9	16.2 27.1	16.0 27.2	0.1	14.4 47.9	8.5	4.1
Other income	0.5	25.5	25.0	0.3	25.3	25.0	4.3	494.5	21.2
Other expenses	4.0	3.1	(1.0)	2.4	2.2	(0.2)	4.0	(22.3)	(0.9)
Operating profit	34.1 110.3	41.9 133.2	22.9	33.7 56.5	45.9 77.9	21.4	39.2 130.6	2.0	2.6
Core operating profit	34.1 110.3	34.1 108.5	(1.8)	33.7 56.5	31.1 52.7	(3.8)	38.2 127.4	(14.8)	(18.8)
Finance income	27.5	28.3	0.8	19.1	15.5	(3.6)	30.5	(7.2)	(2.2)
Finance costs	1.6	1.9	0.3	1.0	1.0	0.0	2.6	(27.2)	(0.7)
Profit before tax	42.1 136.3	50.2 159.6	23.3	44.5 74.7	54.5 92.4	17.7	47.5 158.5	0.7	1.1
Profit attributable to owners of parent	103.6	119.7	16.1	58.7	70.3	11.6	122.2	(2.0)	(2.5)

Revision of earnings forecast

Sales by Segment



(Unit: B yen)

	FY2020 Forecasts Full year			FY2020 Forecasts 2H			FY2019	Y on Y	
	Forecasts (May 11)	Forecast (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Domestic Prescription drugs	123.9	115.3	(8.7)	70.8	68.1	(2.7)	106.3	8.5	9.0
Overseas subsidiaries/export	24.0	24.0	-	12.8	13.0	0.3	30.8	(21.9)	(6.8)
Shionogi Inc.	5.1	6.2	1.1	2.6	2.9	0.3	10.1	(38.7)	(3.9)
C&O	11.9	10.5	(1.4)	6.2	6.2	-	13.1	(20.1)	(2.6)
Contract manufacturing	15.4	17.1	1.6	7.6	10.4	2.8	17.6	(2.9)	(0.5)
OTC and quasi-drug	10.4	11.9	1.4	5.6	6.4	0.8	9.7	22.3	2.2
Royalty income	148.3	148.3	-	70.5	71.0	0.5	166.9	(11.1)	(18.6)
HIV franchise	126.3	126.3	-	62.1	62.4	0.3	128.1	(1.4)	(1.8)
Crestor®	16.9	16.9	-	5.7	5.7	-	22.3	(24.4)	(5.4)
Others	5.2	5.2	-	2.7	2.9	0.2	16.5	(68.7)	(11.3)
Others	1.3	1.5	0.2	0.6	0.7	0.1	2.2	(28.5)	(0.6)
Total	323.5	318.1	(5.4)	167.9	169.6	1.8	333.4	(4.6)	(15.3)

Revenue of Prescription Drugs in Japan



(Unit: B yen)

	FY2020 Forecasts Full year			FY2020 Forecasts 2H			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Cymbalta®	28.6	28.2	(0.4)	14.7	14.7	-	26.2	7.5	2.0
Intuniv®	16.7	15.9	(0.8)	9.8	9.8	-	10.6	49.0	5.2
Vyvanse®**	0.8	0.7	(0.2)	0.6	0.6	-	0.0	- **	0.6**
Infectious disease drugs	26.5	22.8	(3.7)	19.4	17.9	(1.4)	16.0	42.3	6.8
OxyContin® franchise	5.6	5.4	(0.1)	2.7	2.7	-	5.8	(6.9)	(0.4)
Symproic®	2.9	2.7	(0.2)	1.6	1.6	-	2.1	26.7	0.6
Actair®	0.3	0.3	(0.0)	0.2	0.2	-	0.3	23.2	0.1
Mulpleta®	0.1	0.1	(0.0)	0.1	0.1	-	0.1	(9.9)	(0.0)
Pirespa®	4.9	4.8	(0.0)	2.0	2.0	-	6.8	(28.4)	(1.9)
Others	37.5	34.4	(3.2)	19.8	18.5	(1.3)	38.3	(10.2)	(3.9)
Crestor®	8.3	7.8	(0.5)	4.1	4.1	-	8.6	(9.2)	(0.8)
Irbetan® franchise	3.7	3.6	(0.1)	1.9	1.9	-	4.2	(14.4)	(0.6)
Prescription drugs	123.9	115.3	(8.7)	70.8	68.1	(2.7)	106.3	8.5	9.0

<Products included in infectious disease drugs>

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

3. Actions in 2nd Half FY2020 to drive Future Growth

ADHD-family: Intuniv[®], Vyvanse[®]

- **Providing options for ADHD treatment that matches each patient's needs by offering 2 drugs with distinct mechanisms**
 - Intuniv[®]
 - > Focus on providing information about efficacy on Hyperactivity/Impulsivity and rapid onset
 - > Drive recognition as a new option for adult patients
 - Vyvanse[®]
 - > Clearly convey the efficacy and safety profile and deepen understanding of distribution management system

Influenza-family: Xofluza[®], Rapiacta[®], BRIGHTPOC[®] Flu·Neo

- **Fulfilling patient needs via appropriate diagnosis and treatment by timely provision of information to doctors**
 - Providing relief from the distress of influenza symptoms and the anxiety around (co-)infection with SARS-CoV-2 by aiding correct diagnosis is our focus as an infectious diseases company
 - Help decrease the healthcare burden associated with influenza in light of COVID-19 pandemic by contributing to the societal needs of fast diagnosis and treatment by providing appropriate information from influenza virus diagnosis to treatment options
 - > Advocating the value of rapid viral load reduction with Xofluza[®] and Rapiacta[®]

Response to AMR : Cefiderocol



United States

- Designation for New Technology Add on Payment (NTAP)* (Start from Oct. 1)
- Approval for the Treatment of Patients 18 years or older with Hospital-Acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia Caused by Gram-Negative Microorganisms (Sep. 25)



EU

- Approval for the Treatment of Infections due to Gram-Negative Bacteria in Adults (18 years or older) with limited treatment options (Apr. 23)
- Launched in U.K. (Sep. 15)
- Planned to expand to major EU countries (Germany, Italy, Spain, France)
 - Swedish Public Health Agency has entered into an agreement with Shionogi for a new reimbursement model to ensure the availability of cefiderocol (Sep. 2)



Global

- Contribution of Nature Outlook Supplement on AMR (Oct. 21)
 - Advocated policy change to address the public health threat, while introducing cefiderocol as an innovation to AMR

Continued intensive efforts to ensure AMR awareness, appropriate use and patient access.

Overseas business: China, Asia



China/Asia business transformation by Ping An-Shionogi, a joint venture company with Ping An group

Shape the future of healthcare

Largest Big Data and health-tech platform

中国平安 PING AN
金融 · 科技



- **2nd** in the world in health-tech patent applications
- Strong healthcare big data access (including RWD) and AI analytics for maximizing the value and application of data
- Developing AI-based new production & quality management systems(QMS)

Strong distribution platform Supply of Shionogi products

 SHIONOGI



- Close collaboration with China's largest online healthcare platform, enabling an efficient sales model without brokers
- Extensive Partnership with **110,000** pharmacies and over **100,000** in-house medical team(1# in China)
- High quality medicinal drugs, generic drug, OTC

Professional expertise in pharmaceutical business



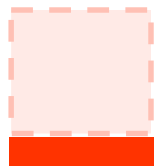
- More than 100 years of R&D experience
- Expertise in Pharmaceutical R&D, manufacturing and distribution
- High proportion of internally-generated pipelines and drug development success

Sales Vision of Ping An-Shionogi



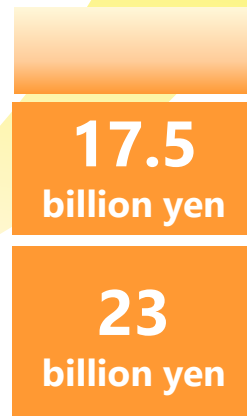
Achieve early profit contributions and stable earnings base to reduce the impact of the coming HIV patent cliff

From FY2020
• Online healthcare collaboration start
• Introducing more than 20 products



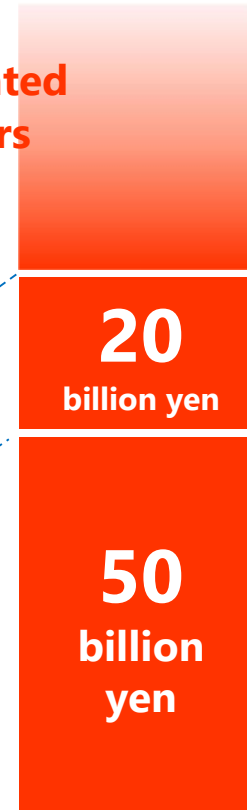
FY2020

FY2022
Cefiderocol approval



FY2022

FY2024
One JV originated candidate enters clinical trial



FY2024

70 billion yen

+ additional sales by strategic investments

Additional sales by strategic investments

Consumer healthcare business in Japan

- Collaboration with online healthcare business
- New drug business in China

Actions to provide comprehensive care for infectious diseases

Prevention



Diagnosis



Treatment



Exacerbation suppression



Immunity acquisition

- Influenza vaccine
- SARS-CoV-2 vaccine
- Pneumococcal vaccine

Appropriate diagnosis

- Influenza diagnosis
- SARS-CoV-2 diagnosis

Elimination/reduction of pathogens

- Therapeutics for severe infection
- Therapeutics for three major infectious diseases
- Therapeutics for influenza virus and COVID-19

Control of host response

- Suppressing overactivation of response systems by targeting host factors

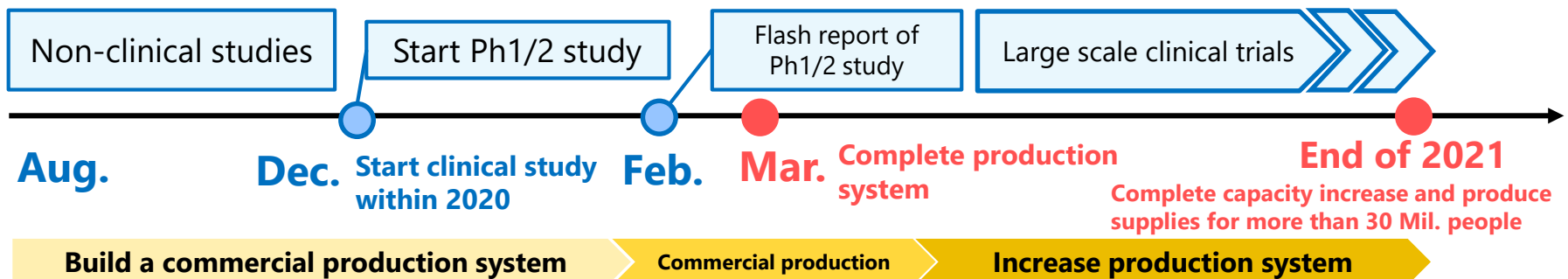
Providing comprehensive infectious disease care to address the medical and societal needs

Our Efforts to Fight COVID-19



Development of Prophylactic Vaccine -1-

- **Developing a recombinant protein vaccine** based on established technology
- Selection of the antigen and the adjuvant completed in collaboration with National Institute of Infectious Diseases and Kyushu University
 - In non-clinical studies, the increase of antigen specific IgG titer and induction of virus neutralizing activity were confirmed
 - **Confirmed aggravation preventive efficacy of vaccination in an animal study (next page)**
- Non-clinical studies are progressing towards clinical trials, planned to **start by the end of 2020**
 - In discussions with regulatory authorities for the design and conduct of large scale clinical trials
- **Complete the 1st phase production system** in collaboration with UNIGEN (API production) and API (Pharmaceutical manufacturing) **within FY2020**
 - Utilizing the grant “Program for Promoting Investment in Japan to Strengthen Supply Chains” by the Ministry of Economy, Trade and Industry
 - Planning to further increase capacity by utilizing the subsidy from the Ministry of Health, Labor and Welfare



Our Efforts to Fight COVID-19



Development of Prophylactic Vaccine -2-

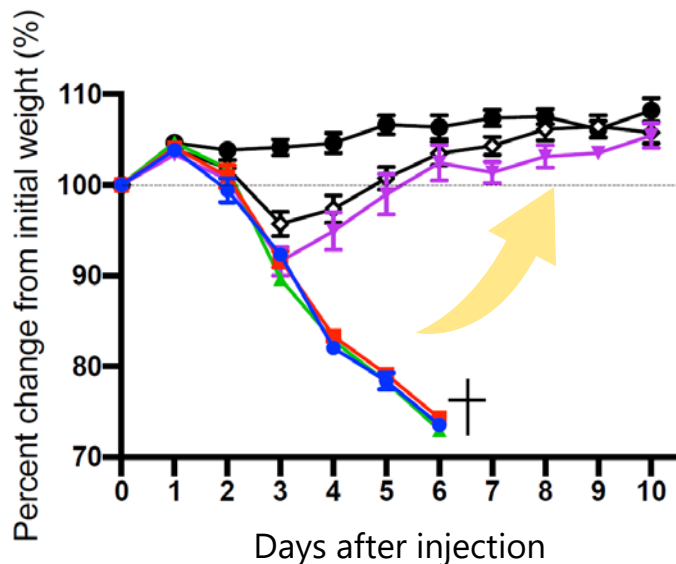
SARS-CoV-2 infection

Vaccinated
animal

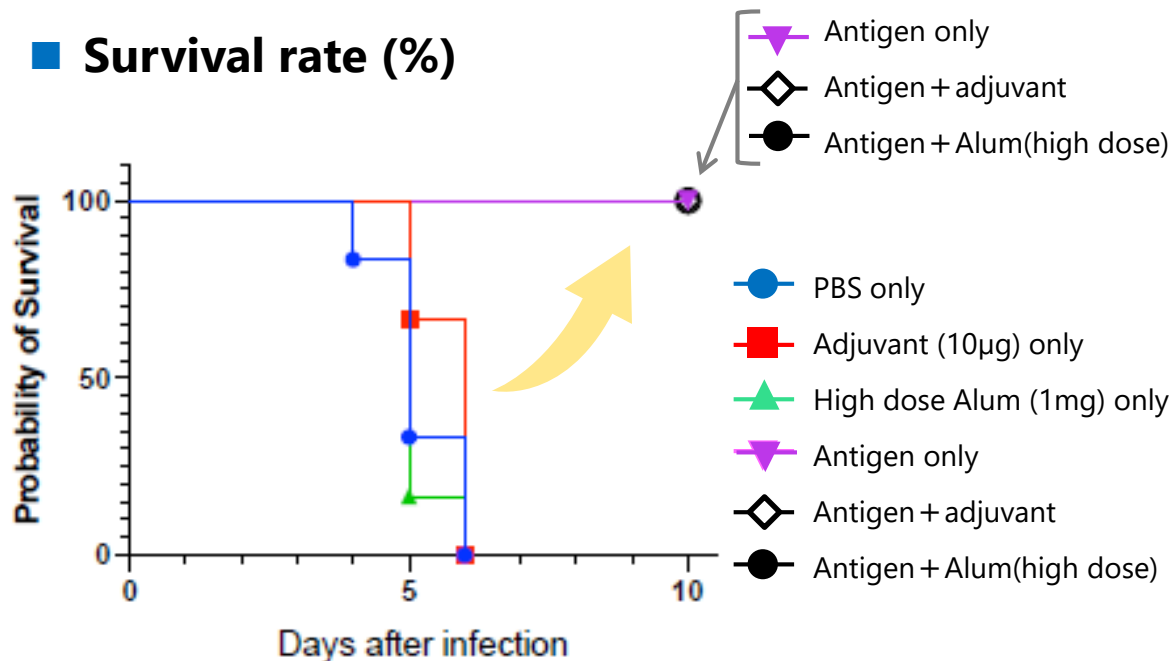
10days follow-up

Confirmed clear aggravation preventive efficacy (from death) in an animal study after vaccination including the selected antigen protein

■ Weight change (%)



■ Survival rate (%)



Our Efforts to Fight COVID-19



Discovery of Novel Therapeutic Drugs

- Advancing collaborative research with Hokkaido Univ. and National Institutes of Biomedical Innovation, Health and Nutrition
- The efficacy and safety studies for the best candidate compound for SARS-CoV-2 were conducted
 - **Abandoned the target of entering clinical study within FY2020** as more efficacy and safety studies are needed
- We **continue efforts of drug discovery** which is active not only for SARS-CoV-2 but for other corona viruses broadly from the standpoint of potential future corona virus pandemic
 - Realizing more effective and safe drug than current repositioned drugs by taking advantage of various modalities



Offering Test/Diagnosis Kit

- Launched IgG/IgM Antibody-test Kit as a research reagent
 - For more convenience, the 20 tests/kit product was produced in exchange for 50 tests/kit.
- License agreement regarding developing a new rapid diagnostic method (SATIC*method) with 3 Univ.**
 - To address the needs of medical settings with this technology***, the initial delivery amount has to be secured.
 - > **The release target of the initial product was changed to December 2020** to focus more on supply system development
 - Acceleration of development and production scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples

Medium to Long Term Direction of Vaccine Businesses



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



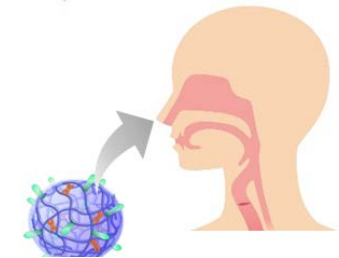
Vaccine

- Established manufacturing technology (BEVS)
- New administration route technology
- Novel adjuvant development

(BEVS : Baculovirus Expression Vector System)

Oct. 31, 2017 Capital and business alliance agreement
Mar. 18, 2020 wholly owned subsidiary

HanaVax



Cationic Nanogel Delivery System*

Sep. 30, 2020 License agreement of nasal Pneumococcal vaccine

Infectious diseases with no effective preventive method

Unmet needs with current vaccines

Versatile and competitive new vaccines

adjuvant

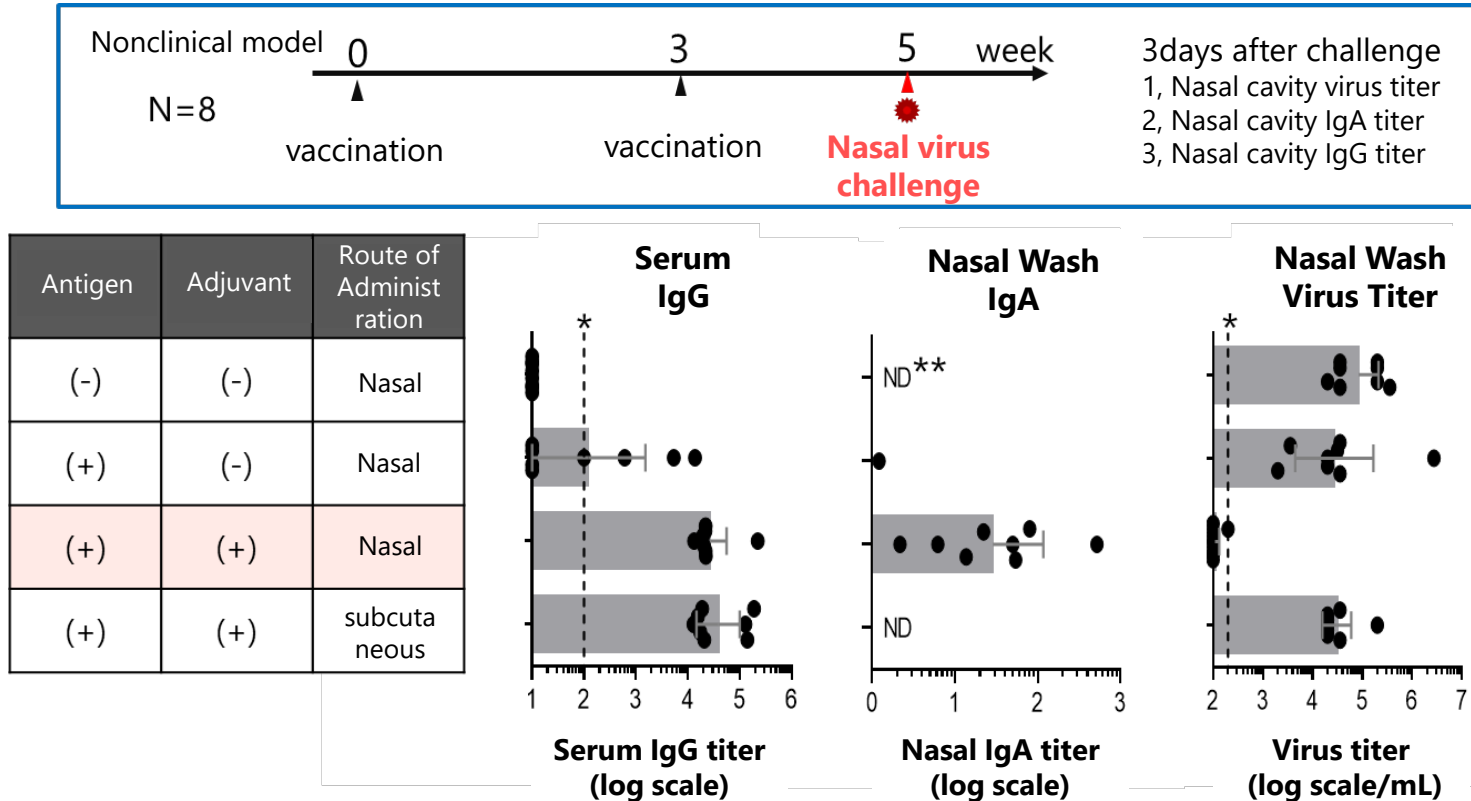
Formulation technology

New administration route technology

- Simple nasal administration by cationic nanogel delivery formulation
- Prevent initial infection

S-872600 : Nasal Influenza Vaccine

Prevention from influenza virus challenge by nasal vaccination



Contribute to global health and pandemic containment by providing effective preventive vaccines as a part of comprehensive care for infectious diseases

R&D : Progress of Core Pipeline Assets



S-600918

Refractory chronic cough

Phase 2b study in progress
⇒ Topline result expected Q1 FY2021

Sleep apnea syndrome

Phase 2a study in progress
⇒ Topline result expected Q1 FY2021

steady progress of patient recruitment

Neuropathic pain

Phase 1

Redasemtide (S-005151)

Epidermolysis bullosa

Confirmed efficacy in investigator-initiated clinical trial
Preparing for application

Acute stroke

Phase 2 study in progress
⇒ Topline result expected Q3 FY2021

New development for indications of 3 diseases

Osteoarthritis

Investigator-initiated clinical trial
Scheduled to start before the end of 2020

Chronic liver disease

Cardiomyopathy

Investigator-initiated clinical trial, Planned

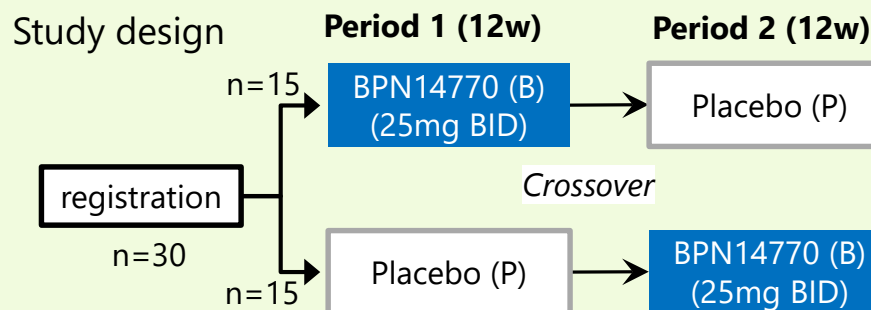
Development of both compounds at top speed for multiple indications in parallel by LCM strategy to maximize value

R&D : Progress of Core Pipeline Assets

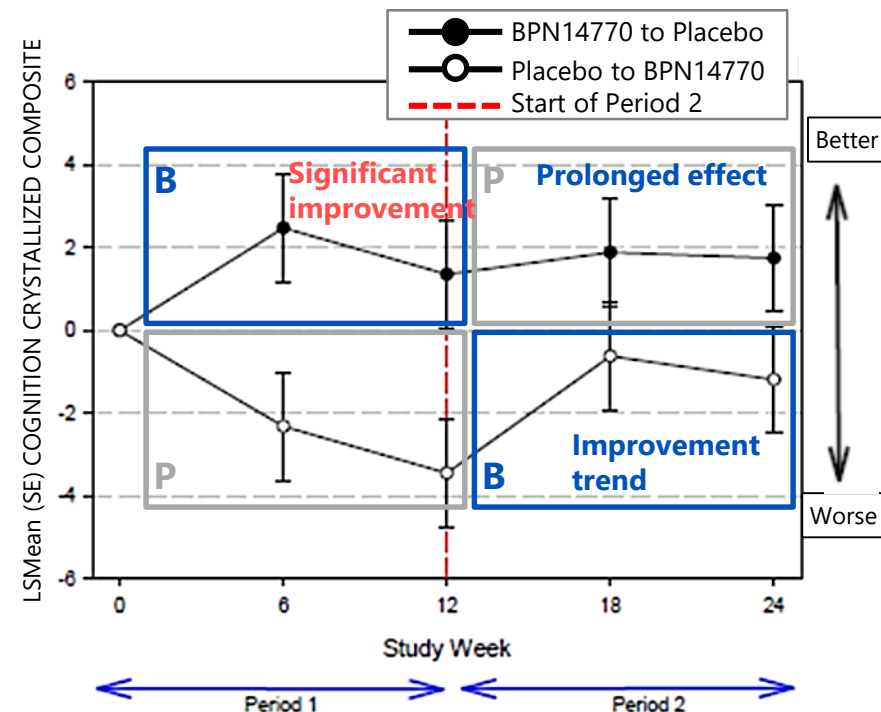
BPN14770 : Positive results in Phase II study for FXS patients

Topline results of U.S. Phase 2 study for the treatment of Fragile X Syndrome (FXS)

- Safety: **No problematic side effects, including no vomiting**
- Efficacy: **Trend toward improvement in cognitive function**
 - Statistically significant improvement of cognitive functions, especially in language-related domain
 - Clinically significant improvement in overall daily function



NIH Toolbox COGNITION CRYSTALLIZED COMPOSITE LSMean Changes from Baseline



Cognitive improvement trend was confirmed not only in Alzheimer's disease patients, but also in Fragile X Syndrome patients, with BPN14770

Zuranolone (S-812217、SAGE-217)

- **Japan**
 - Phase 2 study is in progress for Major Depressive Disorder (MDD)
 - > Steady progress of patient recruitment, topline result expected 3rd quarter FY2021
- **Overseas**
 - Positive interim results of Phase 3 study (SHORELINE study) for adult MDD patients in U.S. conducted by Sage therapeutics



【SHORELINE study】

Study design : 1 year open label study, 1 course regimen* was set as zuranolone 30 mg or 50 mg was administered daily for 14 days

*The need for another treatment course was determined by the assessment of depressive symptoms at the end of each course

Safety, tolerability : No major concern was seen in either the 50 mg group or the 30 mg group

Efficacy : High efficacy was confirmed in both the 30 and 50 mg groups at 15 day point

- 50 mg : response (39 patients, 75.0%), remission (25 patients, 48.1%)
- 30 mg : response (458 patients, 71.6%), remission (255 patients, 39.8%)

Progress of HIV Franchise by ViiV



Commitment of Shionogi

- Combination of two oral drugs that will be the pillar of next-generation HIV treatment
- Creation of the best in class long-acting injections
- Pursue functional cure of HIV infection

Expansion to
“prevention”

Towards
“Cure”

2021~

CAB prophylaxis

- May, 2020 : 66% more effective than FTC/TDF***in preventing HIV infection
→ Anticipated submission 1H 2021

2020~



CABENUVA (CAB/RPV**)

- Jul, 2020 : resubmitted in U.S. (monthly)
→ Scheduled for market launch in Jan.-Mar. 2021
- Oct, 2020 : CHMP recommendation for approval in Europe
Efficacy and safety were confirmed in 5 years of continuous dosing

“Everyday” to
“monthly or
bimonthly”

First long-acting injectable

2019~



Dovato (DTG/3TC*)

- Apr, 2019 : U.S. Approved (new patients)
- Aug, 2020 : U.S. Approved (switch patients)
- Oct, 2020 : Long-term safety and efficacy results from TANGO study 96w, GEMINI study 144w

“3 drug regimen” to
“2 drug regimen”

2017



Juluca

2013



Triumeq



Tivicay

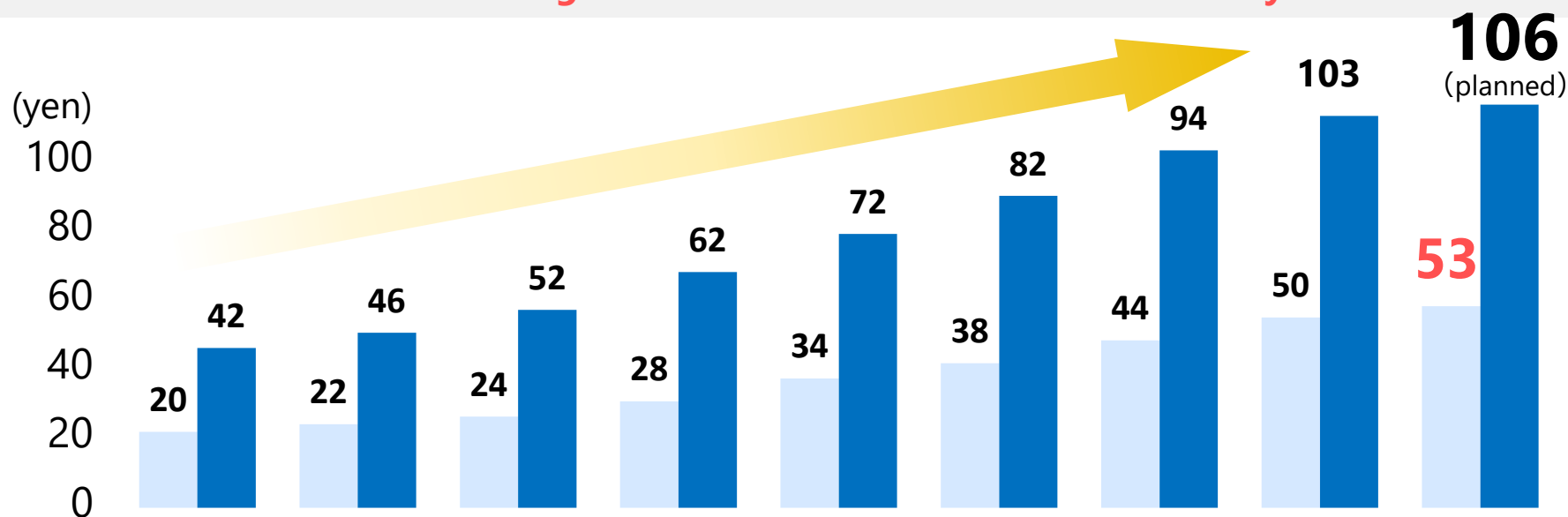
4. Shareholder Return

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 FY2020 for the ninth consecutive year**



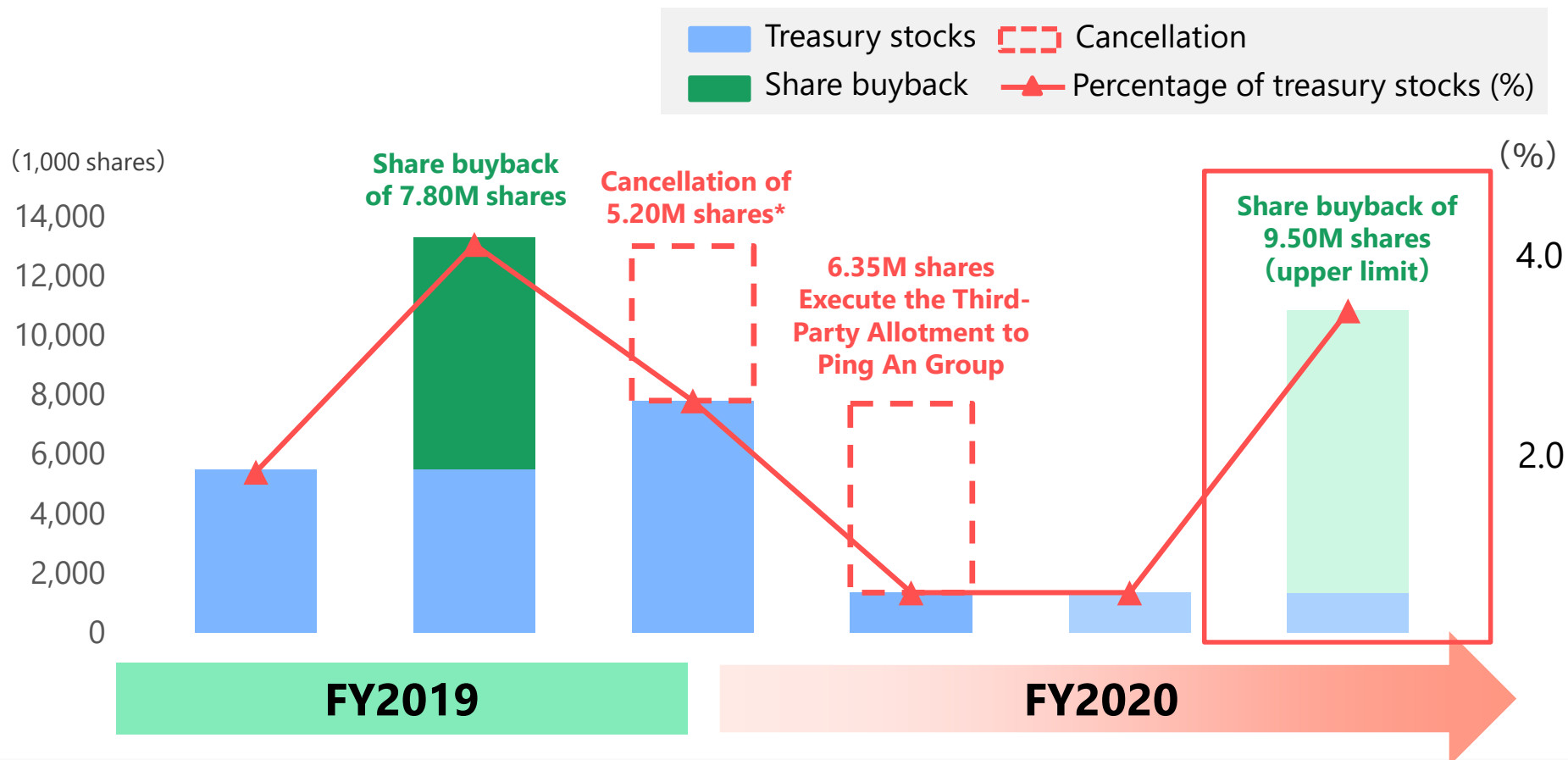
FY		12	13	14	15	16	17	18	19**	20**
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	
	Cancellation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	Over 4.0**
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	Over 12.5**

Share Buyback



Share buyback

- Share buyback : 9.50M shares (upper limit)
- Total amount of buyback: 50 B yen (upper limit)
- Period: Nov. 1, 2020~Mar. 31, 2021



Appendix

Revision of earnings forecast

(excluding a gain on exchange of Shibuya Building (22.9 B yen))



(Unit: B yen)

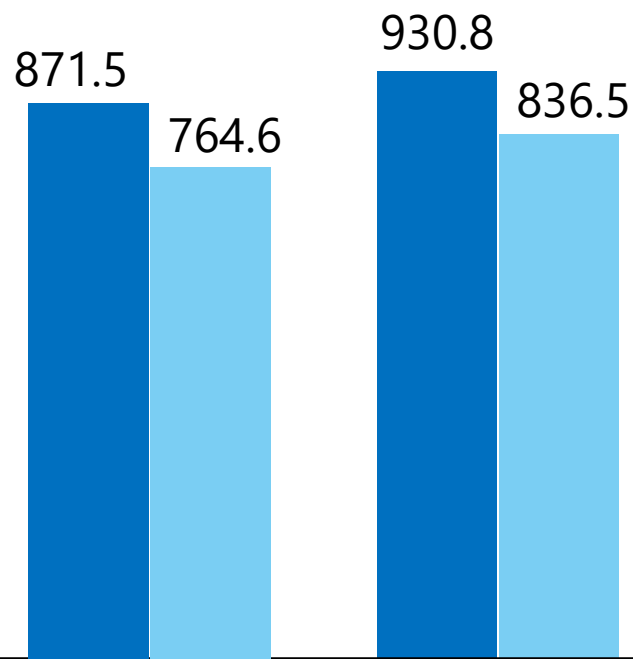
	FY2020 Forecasts Full year			FY2019	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 30)	Revised amount	Results*	Change (%)	Change (B yen)
Revenue	323.5	318.1	(5.4)	333.4	(4.6)	(15.3)
Operating profit	110.3	110.3	-	130.6	(15.5)	(20.3)
Core operating profit**	110.3	108.5	(1.8)	127.4	(14.8)	(18.8)
Profit before tax	136.3	136.7	0.4	158.5	(13.8)	(21.8)
Profit attributable to owners of parent	103.6	103.6	-	122.2	(15.2)	(18.6)

Financial Position (Consolidated, IFRS)



■ Total Assets ■ Equity attributable to owners of parent

(Unit: B yen)

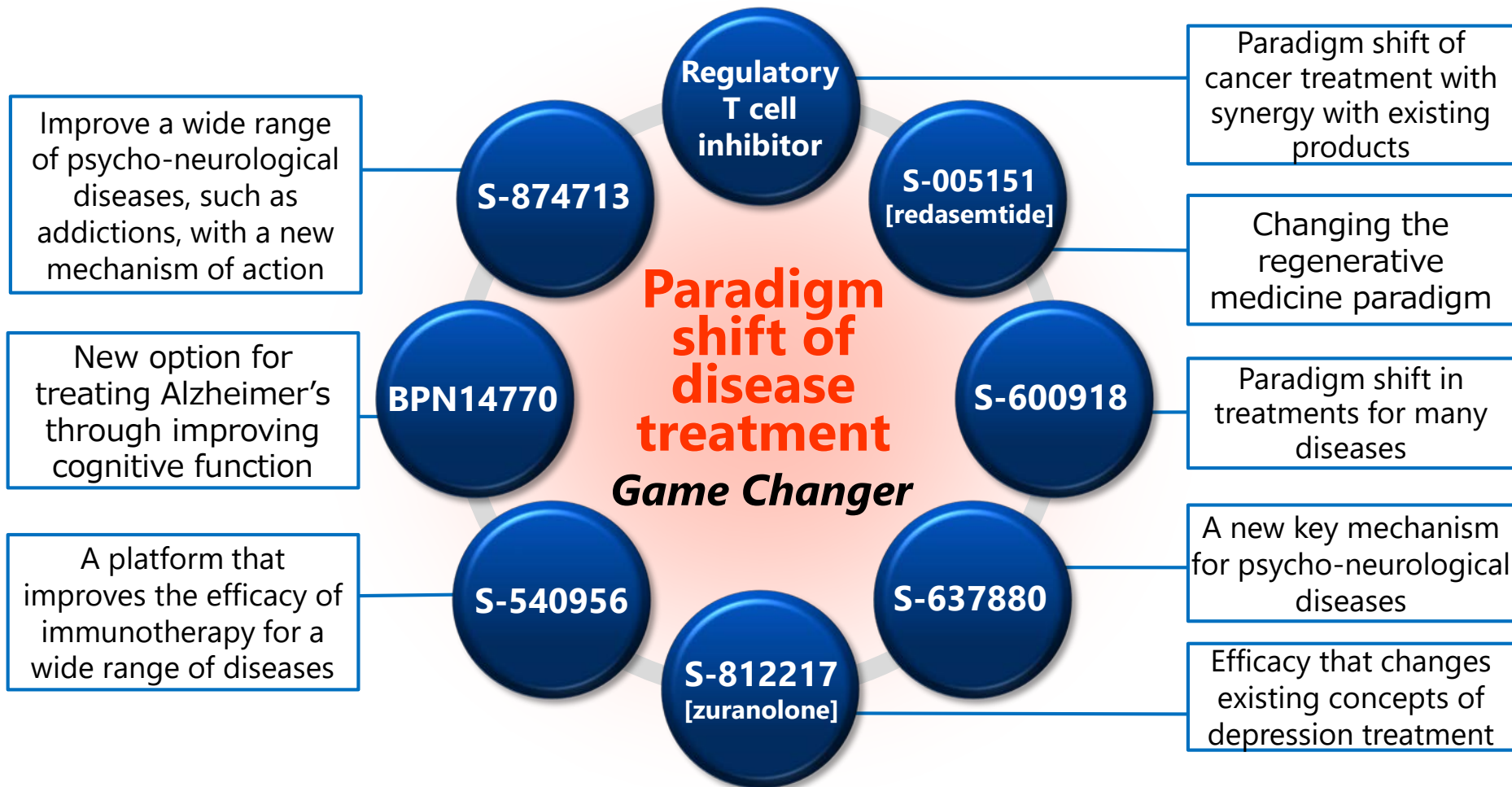


End of Mar. 2020 **End of Sep. 2020**

Unit: B yen		End of Mar. 2020	End of Sep. 2020	Change
Total Assets	Non-current Assets	355.5	368.5	13.0
	Current Assets	516.0	562.4	46.4
Equity attributable to owners of parent		764.6	836.5	71.9
Total Liabilities	Non-current Liabilities	25.8	22.3	(3.5)
	Current Liabilities	81.1	72.1	(9.0)

	Mar. 2020	Sep. 2020
Ratio of equity attributable to owners of parent to total assets	87.7%	89.9%

The Outcome We Envision from our Core Pipeline

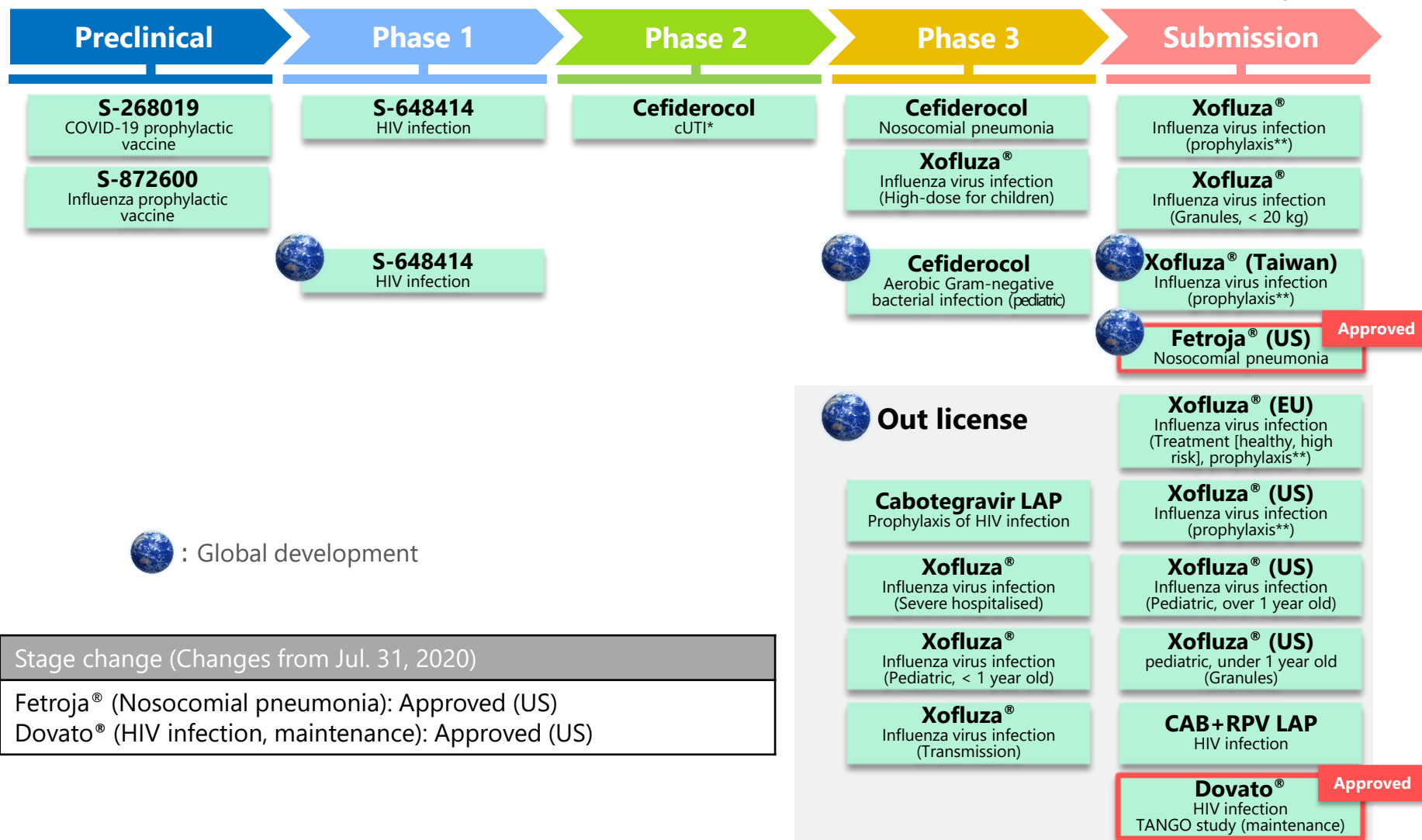


**Creating products and services for diseases
with high unmet medical needs**

Pipeline: Infectious Disease



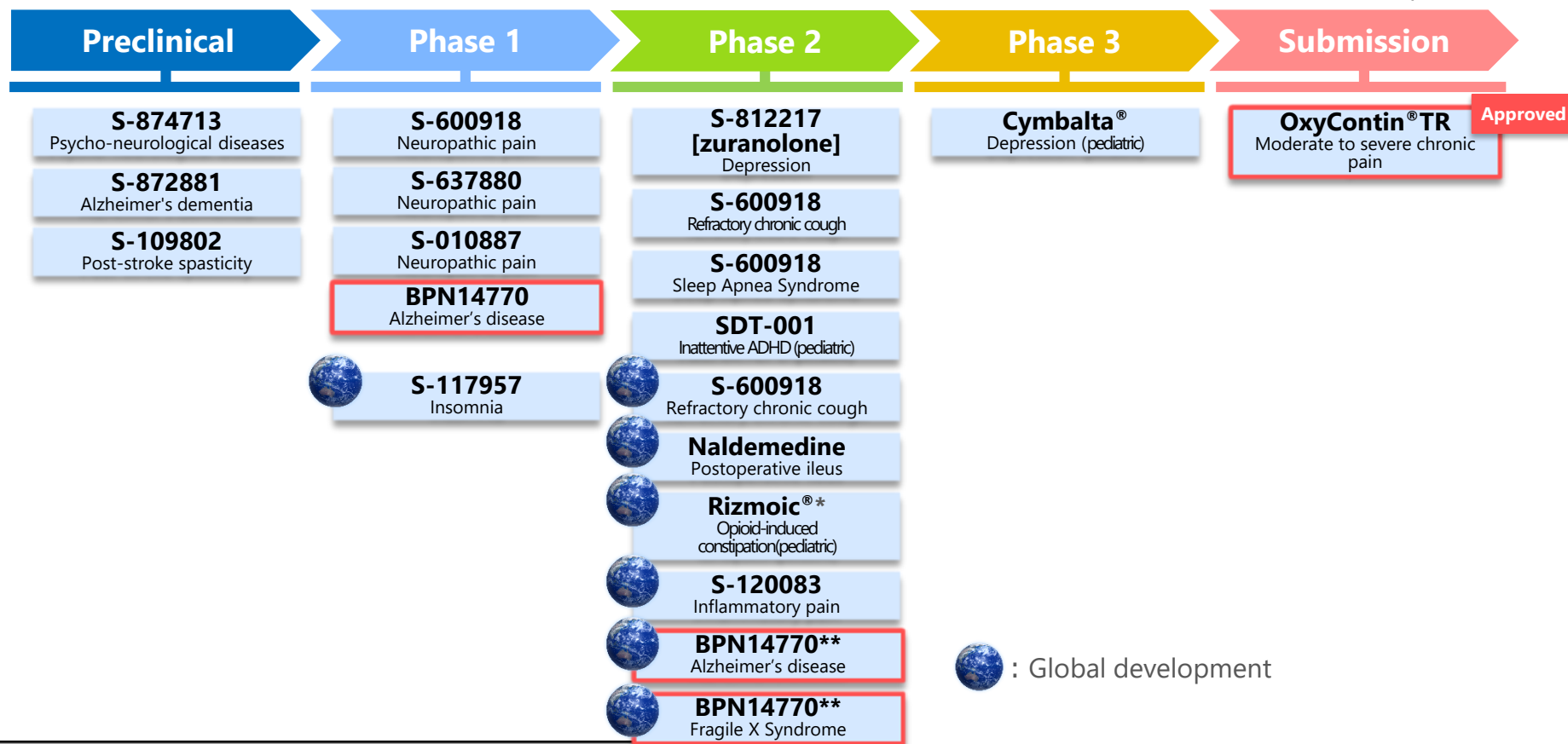
as of Oct 30, 2020



Pipeline: Psycho-neurological Disease



as of Oct 30, 2020



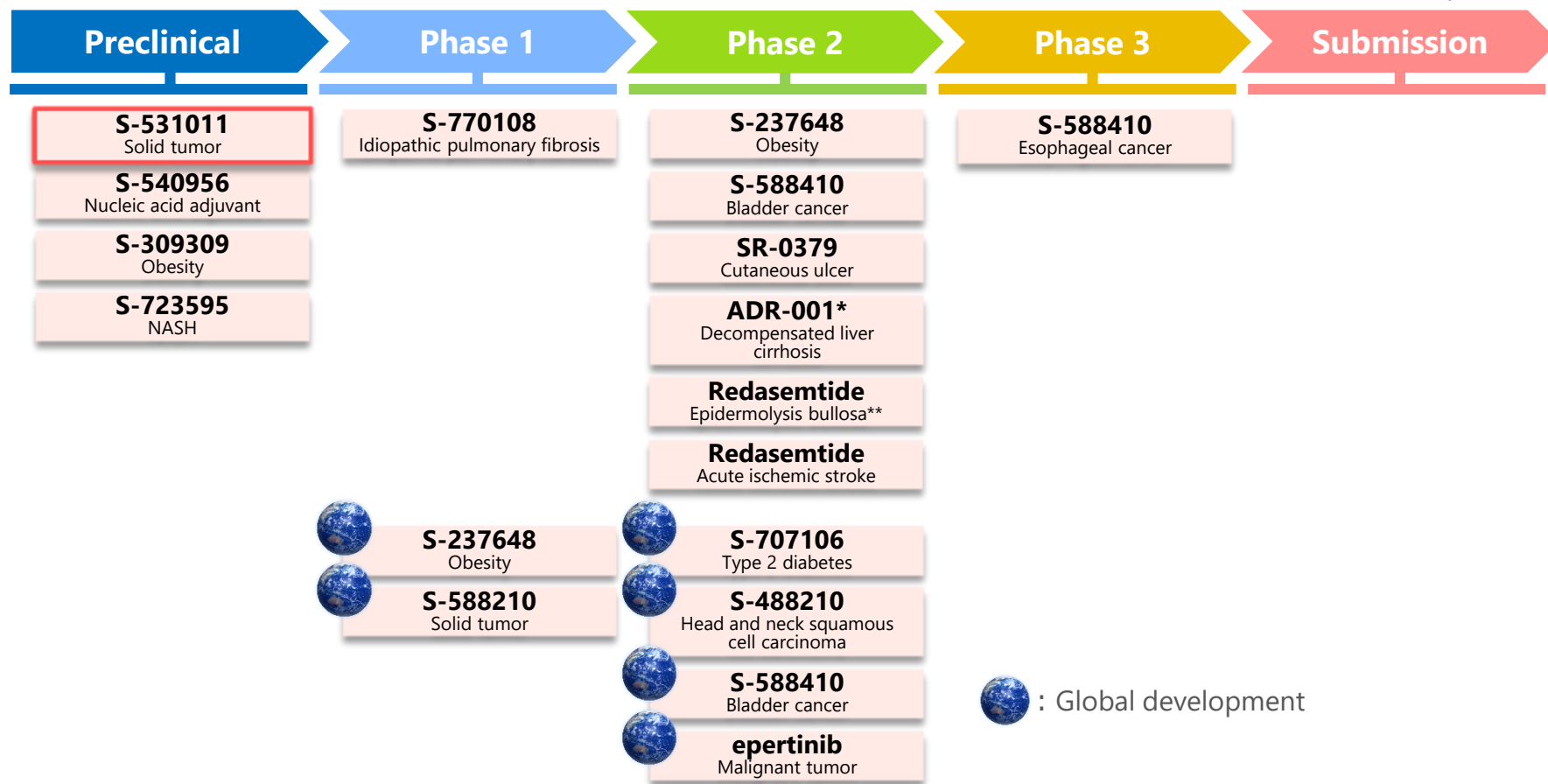
Stage change (Changes from Jul. 31, 2020)

OxyContin® TR (Moderate to severe chronic pain): Approved (Japan)
 BPN14770 (Alzheimer's disease): Phase I (Japan)
 BPN14770 (Alzheimer's disease): Phase II (US)**
 BPN14770 (Fragile X Syndrome): Phase II (US)**

Pipeline: New Growth Area



as of Oct 30, 2020



Stage change (Changes from Jul. 31, 2020)

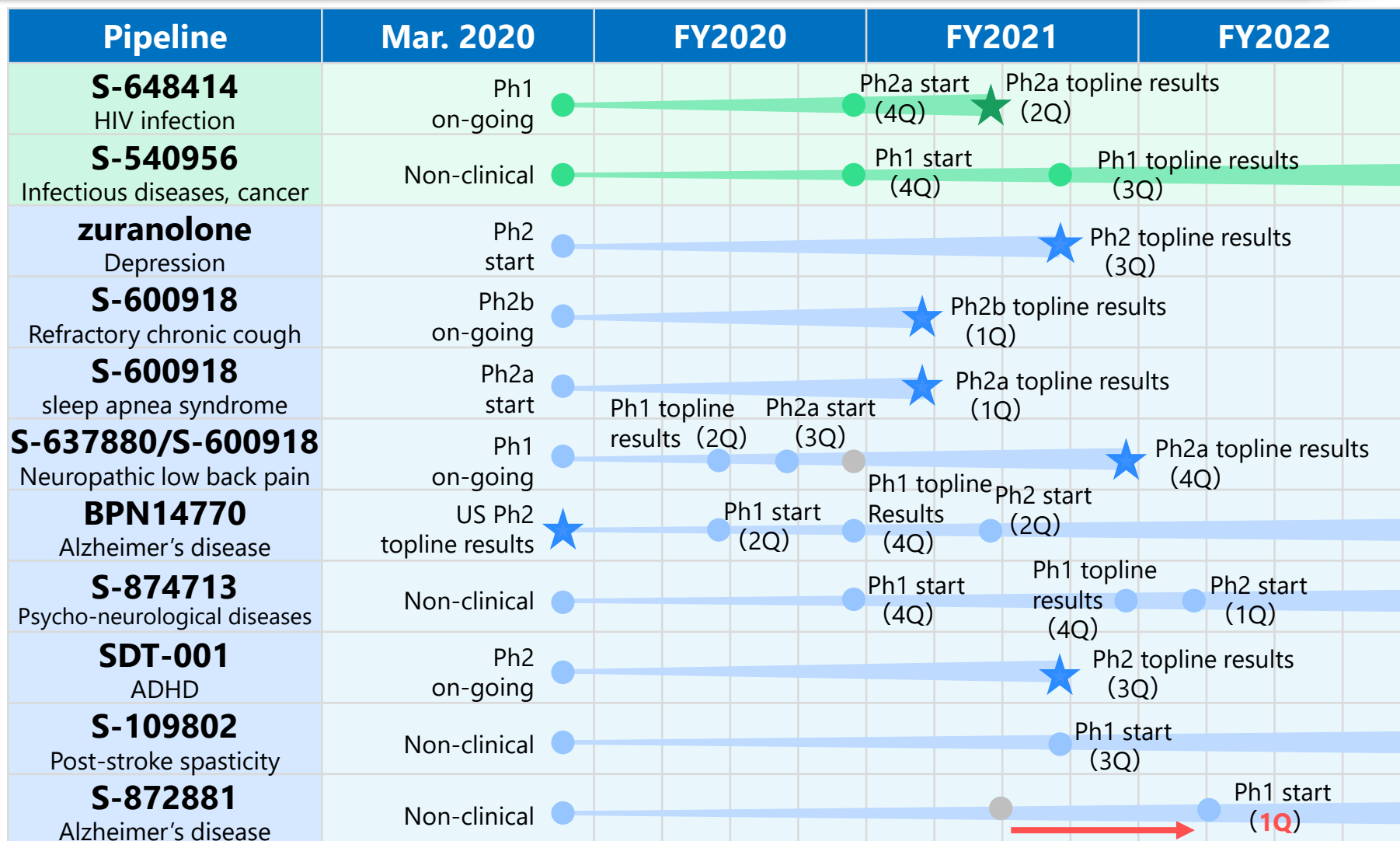
Regulatory T cell inhibitor: development number assigned

FY2020 Pipeline Target Milestones



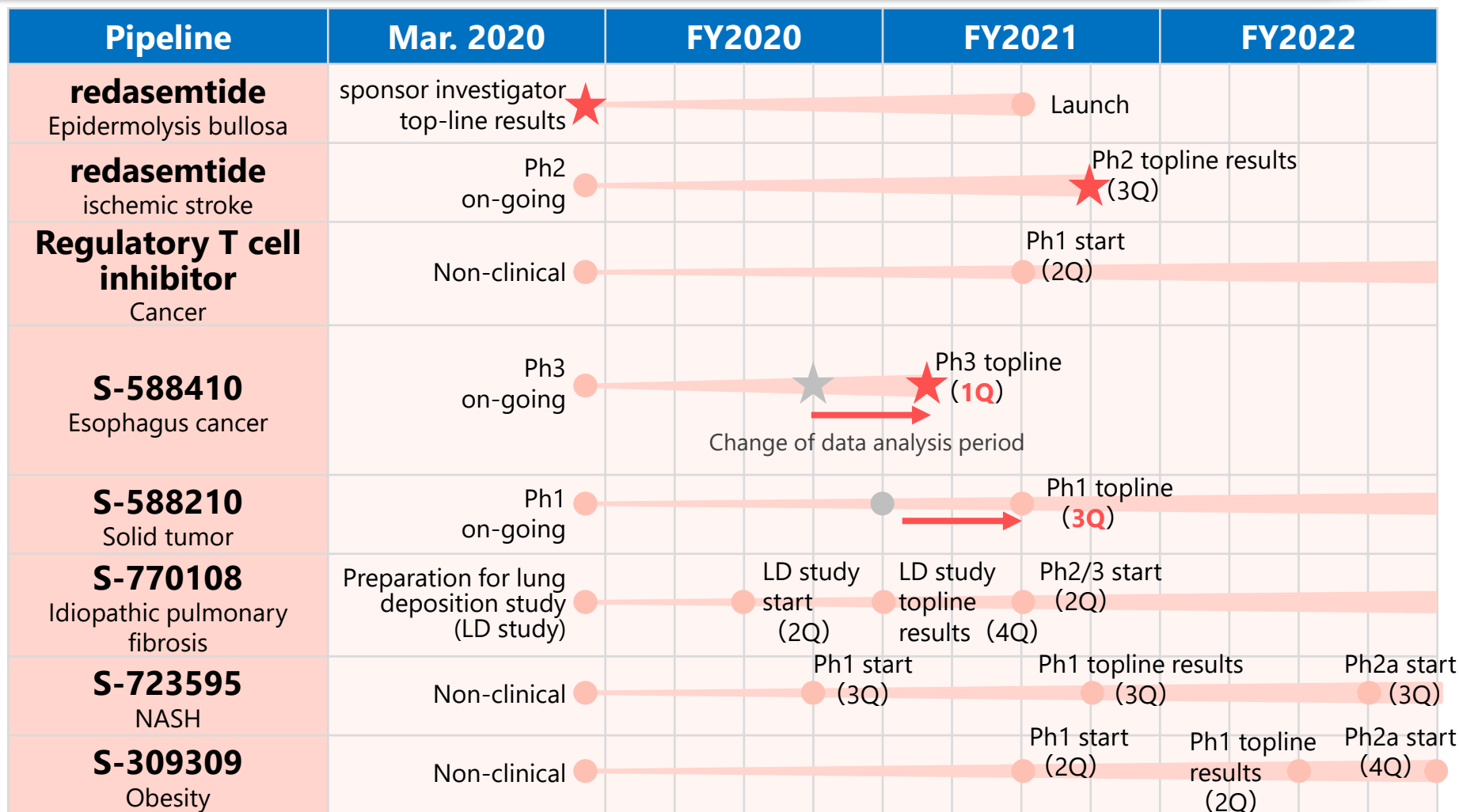
Phase	Pipeline	Indication	Milestone	✓ : achieved
Submission~ Approval	Fetroja® (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval	✓
	Fetroja® (cefiderocol)	Aerobic Gram-negative bacterial infection*	EU: Approval	✓
	Xofluza® granule	Influenza virus infection (pediatric, <20 kg)	Japan: supplemental approval	
	Xofluza®	Influenza virus infection (prophylaxis**)	Japan: supplemental approval	
	Oxycontin® TR	Analgesia in chronic pain	Japan: supplemental approval	✓
	Cymbalta®	Depression (pediatric)	Japan: Submission	
Phase 1~3	S-637880	Neuropathic pain	Japan: Completion of Phase 1 MAD	
	S-600918/S-637880	Neuropathic pain	Japan: Initiation of Phase 2	
	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	Initiation of Phase 1 (Region Not Decided)	
	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	

Key Events for Major Pipeline Compounds



★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and way are considered separately)

Key Events for Major Pipeline Compounds



★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and way are considered separately)

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.
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