1st Quarter of Fiscal 2018 Financial Results

Conference Call

July 30, 2018

SHIONOGI

Agenda

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2. **Upward Revision of Consolidated Forecasts (P.12-15)**
3. **Shareholder Return (P.16-17)**
4. **Progress of Strategic Investments & Pipeline (P.18-24)**

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1. Overview of 1Q FY2018 Financial Results

1Q FY2018 Financial Results

1. **Overview of 1Q FY2018 Financial Results**
2. Upward Revision of Consolidated Forecasts
3. Shareholder Return
4. Progress of Strategic Investments & Pipeline

Financial Results (Consolidated)

(Unit: B yen)

	FY2018				FY2017	Y on Y	
	Forecasts*		1Q results	Achievement	1Q results	Change (%)	Change (B yen)
	Full year	1H					
Sales	346.5	164.0	**88.5**	54.0%	75.0	18.0%	13.5
Operating income	119.0	44.5	**27.6**	62.1%	16.0	72.9%	11.7
Ordinary income	140.0	54.5	**37.9**	69.6%	21.1	80.1%	16.9
Profit attributable to owners of parent	111.0	43.1	**31.9**	74.0%	16.0	99.2%	15.9

- **Sales and each profit measure are progressing smoothly toward 1H forecasts**
- **Each profit measure was higher than the levels achieved in prior 1Q results for:**
  - **Ordinary income: 8 consecutive years**
  - **Profit attributable to owners of parent: 3 consecutive years**

Exchange rate (average)	FY2018 forecasts	1Q FY2018 results
USD ($) – JPY (¥)	105.0	109.11
GBP (£) – JPY (¥)	145.0	148.52
EUR (€) – JPY(¥)	130.0	130.04

* Forecasts announced on May 9, 2018 (Revision was announced on July 23, 2018)

Statement of Income

(Unit: B yen)

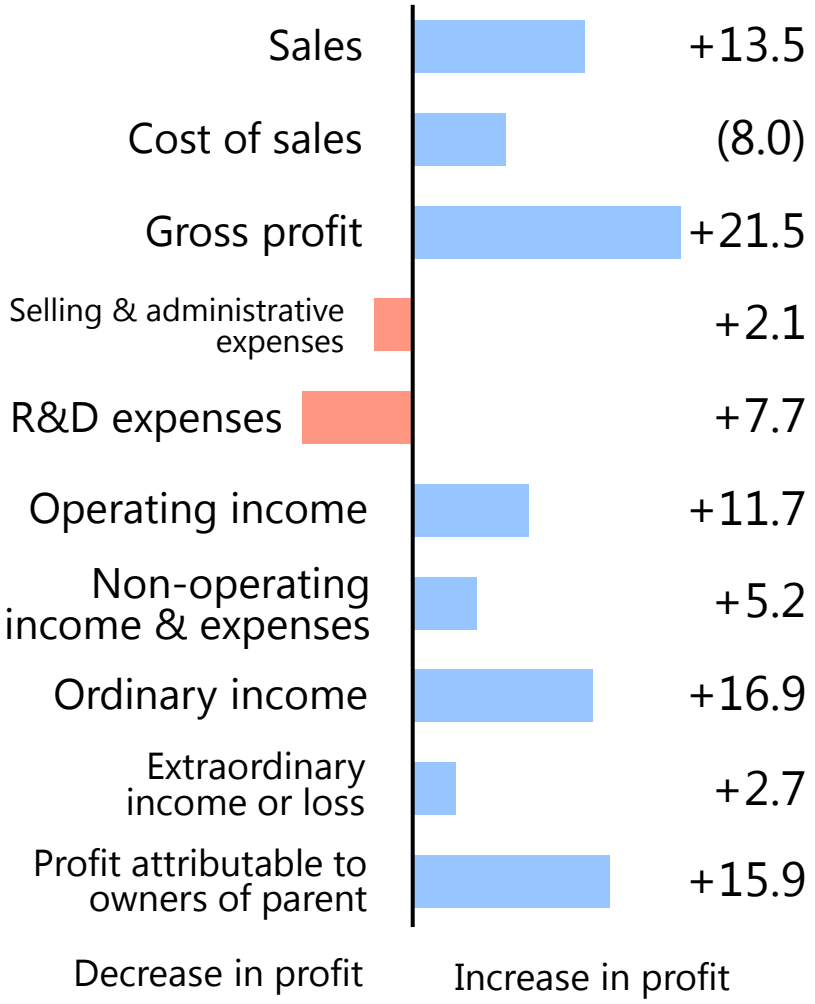
	FY2018				FY2017	Y on Y	
	Forecasts*		1Q results	Achievement (%)	1Q results	Change (%)	Change (B yen)
	Full year	1H					
Sales	**346.5**	**164.0**	**88.5**	54.0	75.0	18.0	13.5
	16.7	16.5	13.5		26.5		
Cost of sales	**58.0**	**27.0**	**11.9**	44.1	19.9	(40.2)	(8.0)
Gross profit	**288.5**	**137.0**	**76.6**	55.9	55.1	39.0	21.5
	48.9	56.4	55.3		52.1		
SG&A expenses	**169.5**	**92.5**	**49.0**	52.9	39.1	25.2	9.8
Selling & administrative expenses	29.6	32.0	27.4		29.5		
	102.5	**52.5**	**24.3**	46.2	22.1	9.7	2.1
	19.3	24.4	27.9		22.7		
R&D expenses	**67.0**	**40.0**	**24.7**	61.8	17.0	45.3	7.7
Ordinary R&D expenses**	**47.0**	**25.0**	**13.7**	54.7	17.0	(19.6)	(3.3)
Strategic investment	**20.0**	**15.0**	**11.0**	73.5	-	-	11.0
	34.3	27.1	31.2		21.3		
Operating income	**119.0**	**44.5**	**27.6**	62.1	16.0	72.9	11.7
Non-operating income & expenses	**21.0**	**10.0**	**10.3**	103.0	5.1	102.6	5.2
	40.4	33.2	42.9		28.1		
Ordinary income	**140.0**	**54.5**	**37.9**	69.6	21.1	80.1	16.9
Profit attributable to owners of parent	**111.0**	**43.1**	**31.9**	74.0	16.0	99.2	15.9

* Forecasts announced on May 9, 2018(Revision was announced on July 23, 2018)
** Ordinary R&D expenses: Total R&D expenses excluding strategic investment

Y on Y Comparison and Main Variation Factors (Statements of Income)

- **Y on Y comparison**

(Unit: B yen)



Main Variation Factors (Y on Y)

- **Sales**
  - Income from Roche for Xofluza®*
  - Increase in royalty income for HIV franchise
  - One-time payment from Purdue for the termination of the prior alliance for Symproic®
  - Decrease in sales of prescription drugs in Japan
- **Cost of sales**
  - Japan business: sales decline and changes in the lineup of major products
  - Decrease in contract manufacturing
- **SG & A expenses**
  - Selling & administrative expenses
    - › Investment in new products (preparation for launch etc.)
    - › Upfront investment in IT
  - R&D expenses
    - › Ordinary R&D expenses: decreased due to completion of Xofluza® OwH** study in FY2017 (-3.3 B yen)
    - › Strategic investment: net increase (11.0 B yen)
- **Non-operating income & expenses**
  - Increase in ordinary dividend due to sales growth of HIV franchise plus impact of one-time change
- **Extraordinary income or loss**
  - Sale of the Nanjing factory of C&O in China

* Royalty income from Roche at milestones of R&D achievement

** OwH: Otherwise healthy

Sales by Segment

(Unit: B yen)

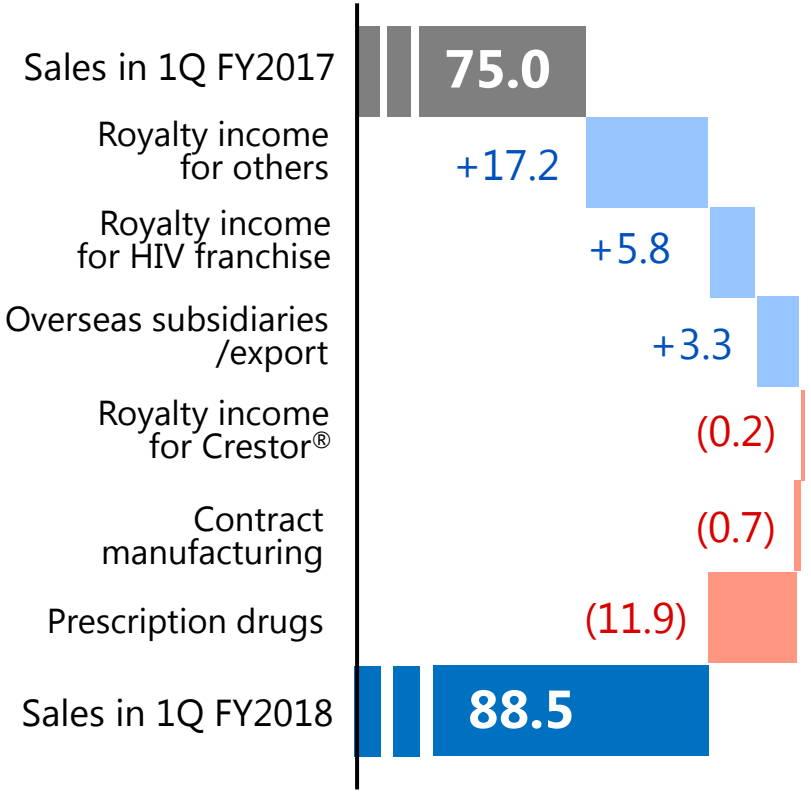
	FY2018				FY2017	Y on Y	
	Forecasts*		1Q results	Achievement (%)	1Q results	Change (%)	Change (B yen)
	Full year	1H					
Prescription drugs	**119.3**	**52.3**	**25.4**	48.6	37.3	(31.9)	(11.9)
Overseas subsidiaries/export	**29.8**	**13.6**	**9.9**	72.4	6.6	49.3	3.3
Shionogi Inc.	**10.9**	**5.0**	**6.1**	120.8	3.5	75.7	2.6
Osphena®	**4.1**	**2.1**	**0.8**	36.7	1.1	(32.7)	(0.4)
C&O	**12.4**	**5.8**	**2.4**	40.4	1.8	31.0	0.6
Contract manufacturing	**12.1**	**5.6**	**2.8**	50.1	3.5	(20.5)	(0.7)
OTC and quasi-drug	**7.4**	**3.4**	**1.6**	46.7	1.6	1.3	0.0
Royalty income	**175.5**	**87.8**	**48.3**	55.0	25.5	89.7	22.9
HIV franchise	**124.9**	**58.7**	**24.5**	41.7	18.6	31.4	5.8
Crestor®	**21.1**	**10.6**	**5.5**	51.9	5.7	(4.3)	(0.2)
Others	**29.5**	**18.5**	**18.3**	99.0	1.1	1,582.1	17.2
Others	**2.5**	**1.3**	**0.6**	45.9	0.6	1.8	0.0
Total	**346.5**	**164.0**	**88.5**	**54.0**	**75.0**	**18.0**	**13.5**

* Forecasts announced on May 9, 2018 (Revision was announced on July 23, 2018)

Y on Y Comparison and Main Variation Factors (Sales by Segment)

- **Y on Y comparison**

(Unit: B yen)



Main Variation Factors
(Y on Y change: +13.5 B yen, +18.0%)

- **Royalty income**
  - Income from Roche for Xofluza®*
  - Sales growth of HIV franchise
- **Overseas subsidiaries/export**
  - **US business**
    - One-time payment from Purdue for the termination of the prior alliance for Symproic®
    - Decrease in royalty income from an authorized generic
- **Prescription drugs**
  - Sales growth of strategic products
  - Sales decrease of Crestor® and Irbetan® due to share capture by generic competitors
  - Sales decrease due to NHI price revision

* Royalty income from Roche at milestones of R&D achievement

Changes in Distribution Platform for Symproic® in the US

- Drastic changes in the environment for opioid use in the US
  - In Oct 2017, the President Trump declared 'the opioid epidemic is a national public health emergency' due to the increases of opioid abuse and deaths with overdosing
- Purdue Pharma L.P. took significant steps to transform their business model in the US
- **Terminated the prior alliance for the co-commercialization of Symproic® in the US: Shionogi regained full rights to Symproic®**
  - **One-time payment from Purdue for the termination of the alliance**

Shionogi Inc. has begun its own sales and distribution of Symproic®, and is seeking a new partner with strong commercial capabilities

Sales of Prescription Drugs in Japan

(Unit: B yen)

	FY2018				FY2017	Y on Y	
	Forecasts*		1Q results	Achievement (%)	1Q results	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta®	26.0	12.1	6.1	50.3	5.8	6.1	0.4
Intuniv®	5.0	1.9	1.1	57.3	0.36	209.9	0.8
Xofluza®	13.0	1.3	0.03	2.6	-	-	-
Rapiacta®	1.1	0.06	0.01	22.3	0.05	(76.4)	0.0
Brightpoc® Flu	1.1	0.11	0.01	4.5	0.05	(90.5)	0.0
OxyContin® franchise	9.1	4.2	2.0	47.3	2.4	(15.2)	(0.4)
Symproic®	1.2	0.48	0.31	65.0	0.05	526.3	0.3
Total of strategic products	56.5	20.3	9.6	47.3	8.6	11.0	1.0
Actair®	0.15	0.06	0.04	68.2	0.03	47.4	0.0
Mulpleta®	0.23	0.12	0.05	39.9	0.05	0.6	0.0
Pirespa®	6.0	3.1	1.4	44.7	1.4	(5.1)	0.0
Total of new products	62.8	23.5	11.0	47.0	10.1	8.8	0.9
Crestor®	9.7	5.3	2.6	49.6	12.1	(78.1)	(9.4)
Irbetan® franchise	6.4	3.6	1.9	53.8	3.7	(48.5)	(1.8)
Others	40.4	19.9	9.8	49.2	11.4	(13.8)	(1.6)
Prescription drugs	**119.3**	**52.3**	**25.4**	**48.6**	**37.3**	**(31.9)**	**(11.9)**

* Forecasts announced on May 9, 2018 (Revision was announced on July 23, 2018)

Growth by Strategic Products

Cymbalta®

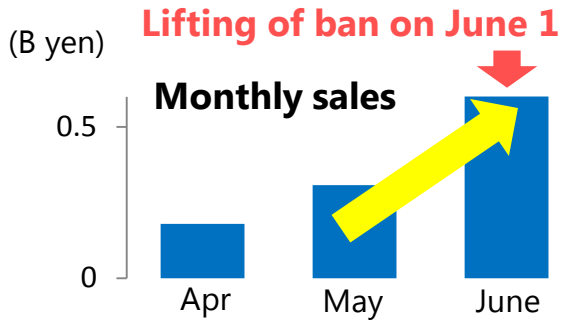
- Smooth prescription increase in CNS field

➡ **Y on Y increase by ca. 20%**

Intuniv®

- Significant increase in sales effort in 1Q prior to the lifting of ban on long-term treatment on June 1, 2018

➡ **Sales of Intuniv® have increased substantially**



Influenza family (Xofluza®, Rapiacta®, Brightpoc®Flu, Brightpoc® Flu・Neo)

- Launch of Brightpoc® Flu·Neo
  - High sensitivity* and rapid diagnosis
- Provide timely and accurate information for diagnosis and treatment



➡ **Strengthening the support for Influenza Family prior to the 2018-19 flu season**

* The correlation test between the diagnosis results of 'Brightpoc®Flu・Neo' and the results of virus isolation culture method resulted in the agreement rates of 95.3% for type A and 96.7% for type B using nasal swabs; and 93.3% for type A and 99.1% for type B using samples aspirated from nasal cavity

2. Upward Revision of Consolidated Forecasts

1Q FY2018 Financial Results

1. Overview of 1Q FY2018 Financial Results
2. **Upward Revision of Consolidated Forecasts**
3. Shareholder Return
4. Progress of Strategic Investments & Pipeline

Major Factors Driving Forecast Changes Since the Beginning of FY2018

- **Acceleration of Xofluza™ HR* study completion**
  - Prospect for income** from Roche to be received ahead of schedule (2H → 2Q)
  - Increase in R&D expenses (1H)
- **US business**
  - Income from Purdue for the termination of the prior alliance for the co-commercialization of Symproic® in US
  - Decrease in royalty income from an authorized generic
- **HIV franchise: Increase in dividend from ViiV, including one-time event (1Q)**

Aiming to further increase in income and profit with expanding investment for new growth drivers

→ Upward revision of forecasts for 1H and full year

* HR: High risk (patients at high risk for influenza-related complications
** Royalty income from Roche at milestones of R&D achievement

Upward Revision of Forecasts
(Announced on July 23, 2018)

(Unit: B yen)

	FY2018 Forecasts						FY2017	Y on Y	
	Full year			1H			Results	Revised	
	Original*	Revised**	Change (B yen)	Original*	Revised**	Change (B yen)		Change (%)	Change (B yen)
Sales	346.5	348.0	1.5	164.0	168.0	4.0	344.7	1.0	3.3
Operating income	119.0	120.0	1.0	44.5	48.0	3.5	115.2	4.1	4.8
Ordinary income	140.0	144.0	4.0	54.5	61.0	6.5	138.7	3.8	5.3
Profit attributable to owners of parent	111.0	114.5	3.5	43.1	48.6	5.5	108.9	5.2	5.6

Increase in sales and profit over the original forecasts

- Y on Y change (B yen)
  - Sales: 1.8 → 3.3
  - Ordinary income: 1.3 → 5.3
  - Operating income: 3.8 → 4.8
  - Net Profit: 2.1 → 5.6

Exchange rate (average)	FY2018 forecasts	1Q FY2018 results
USD ($) – JPY (¥)	105.0	109.11
GBP (£) – JPY (¥)	145.0	148.52
EUR (€) – JPY(¥)	130.0	130.04

* Forecasts announced on May 9, 2018
** Forecasts announced on July 23, 2018

Revision of Statement of Income

	FY2018 forecasts								
	Full year			1H			2H		
	Original*	Revised**	Change (B yen)	Original*	Revised**	Change (B yen)	Original*	Revised**	Change (B yen)
Sales	346.5	**348.0**	**1.5**	164.0	**168.0**	**4.0**	182.5	**180.0**	**(2.5)**
	16.7	**16.5**		16.5	**15.8**		17.0	**17.2**	
Cost of sales	58.0	**57.5**	**(0.5)**	27.0	**26.5**	**(0.5)**	31.0	**310.0**	**0**
Gross profit	288.5	**290.5**	**2.0**	137.0	**141.5**	**4.5**	151.5	**149.0**	**(2.5)**
	48.9	**49.0**		56.4	**55.7**		42.2	**42.8**	
SG&A expenses	169.5	**170.5**	**1.0**	92.5	**93.5**	**1.0**	77.0	**77.0**	**0**
	29.6	**29.3**		32.0	**31.0**		27.4	**27.8**	
Selling & administrative expenses	102.5	**102.0**	**(0.5)**	52.5	**52.0**	**(0.5)**	50.0	**50.0**	**0**
	19.3	**19.7**		24.4	**24.7**		14.8	**15.0**	
R&D expenses	67.0	**68.5**	**1.5**	40.0	**41.5**	**1.5**	27.0	**27.0**	**0**
Ordinary R&D expenses***	47.0	**48.5**	**1.5**	25.0	**26.5**	**1.5**	22.0	**22.0**	**0**
Strategic investment	20.0	**20.0**	**0**	15.0	**15.0**	**0**	5.0	**5.0**	**0**
	34.3	**34.5**		27.1	**28.6**		40.8	**40.0**	
Operating income	119.0	**120.0**	**1.0**	44.5	**48.0**	**3.5**	74.5	**72.0**	**(2.5)**
Non-operating income & expenses	21.0	**24.0**	**3.0**	10.0	**13.0**	**3.0**	11.0	**11.0**	**0**
	40.4	**41.4**		33.2	**36.3**		46.8	**46.1**	
Ordinary income	140.0	**144.0**	**4.0**	54.5	**61.0**	**6.5**	85.5	**83.0**	**(2.5)**
Profit attributable to owners of parent	111.0	**114.5**	**3.5**	43.1	**48.6**	**5.5**	67.9	**65.9**	**(2.0)**

* Forecasts announced on May 9, 2018 ** Forecasts announced on July 23, 2018

*** Ordinary R&D expenses: Total R&D expenses excluding strategic investment

3. Shareholder Return

1Q FY2018 Financial Results

1. Overview of 1Q FY2018 Financial Results
2. Upward Revision of Consolidated Forecasts
3. **Shareholder Return**
4. Progress of Strategic Investments & Pipeline

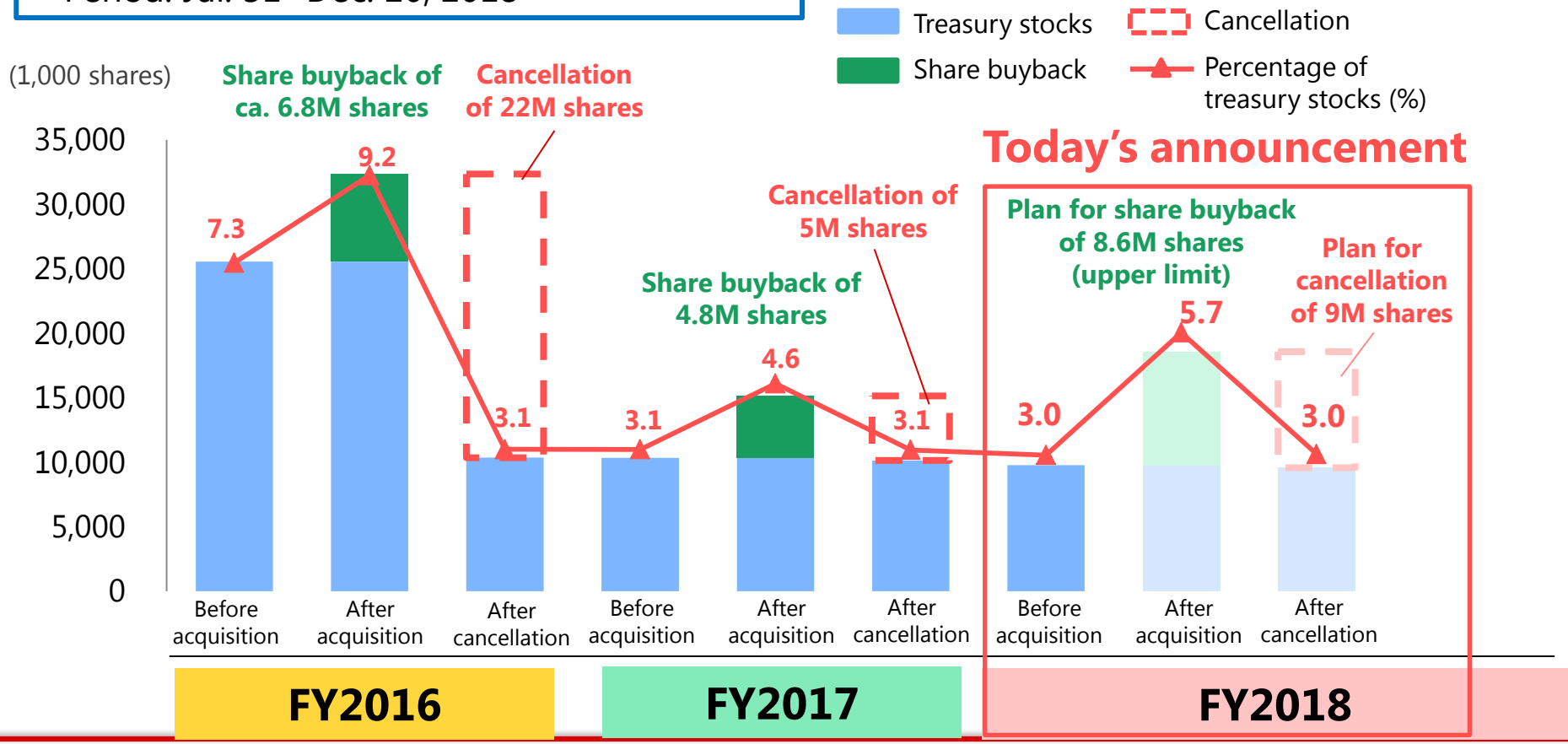
Share Buyback and Cancellation

Share buyback

- Share buyback: 8.6M shares (upper limit)
- Total amount of buyback: 50 B yen (upper limit)
- Period: Jul. 31~Dec. 20, 2018

Cancellation of treasury shares

- Total shares to be cancelled: 9M shares
- Date for cancellation: Jan. 31, 2019



4. Progress of Strategic Investments & Pipeline

1Q FY2018 Financial Results

1. Overview of 1Q FY2018 Financial Results
2. Upward Revision of Consolidated Forecasts
3. Shareholder Return
4. **Progress of Strategic Investments & Pipeline**

Steady Progress of Strategic Investment

- **May 31, 2018: In-licensing & research collaboration with Hsiri**
  - Global rights for discovery and development of novel therapeutics for non-tuberculous mycobacterial (NTM) diseases and tuberculosis

- **June 14, 2018: Strategic collaboration with SAGE**
  - Antidepressant with novel mechanism of action
    - > Exclusive rights for development & commercialization of SAGE-217 in Japan, Taiwan and South Korea
  - Other possible indications: sleep disorder, mood disorder and motor disorder

Strategic investment for sustainable growth beyond 2020 (11 B yen in 1Q)



Hsiri：Novel Drug for Mycobacterial Disease

- **Novel mechanism of action**, efficacy on both tuberculosis and non-tuberculosis mycobacterial disease, potential to fulfill unmet medical needs
- Start R&D for the treatment of NTM Disease

Mycobacterial Disease		
	Tuberculosis (TB)	**NTM Disease*5**
Patient number, Market potential	10.4 M new patients/year*1, ¥43.7 B market worldwide*2	Estimated 90K patients (JP); 180K patients (US) ; 9K patients (EU5)
Challenges for Mycobacterial Disease Treatment	• **One of the world's top 3 infectious diseases** • Multidrug-resistant TB and extensively drug-resistant TB • Long-term treatment • The most common presenting illness among HIV patients	• **No drugs developed for NTM disease, low effectiveness of current treatment** • Long-term treatment (>1 year) • Increased prevalence in developed countries
Action by Shionogi	S-004992, Hsiri molecules, Collaboration with TB ALLIANCE*3, GHIT*4	Hsiri molecules

Enhance presence of Shionogi in infectious disease field including TB through development of S-004992 and Hsiri molecules for mycobacterial disease

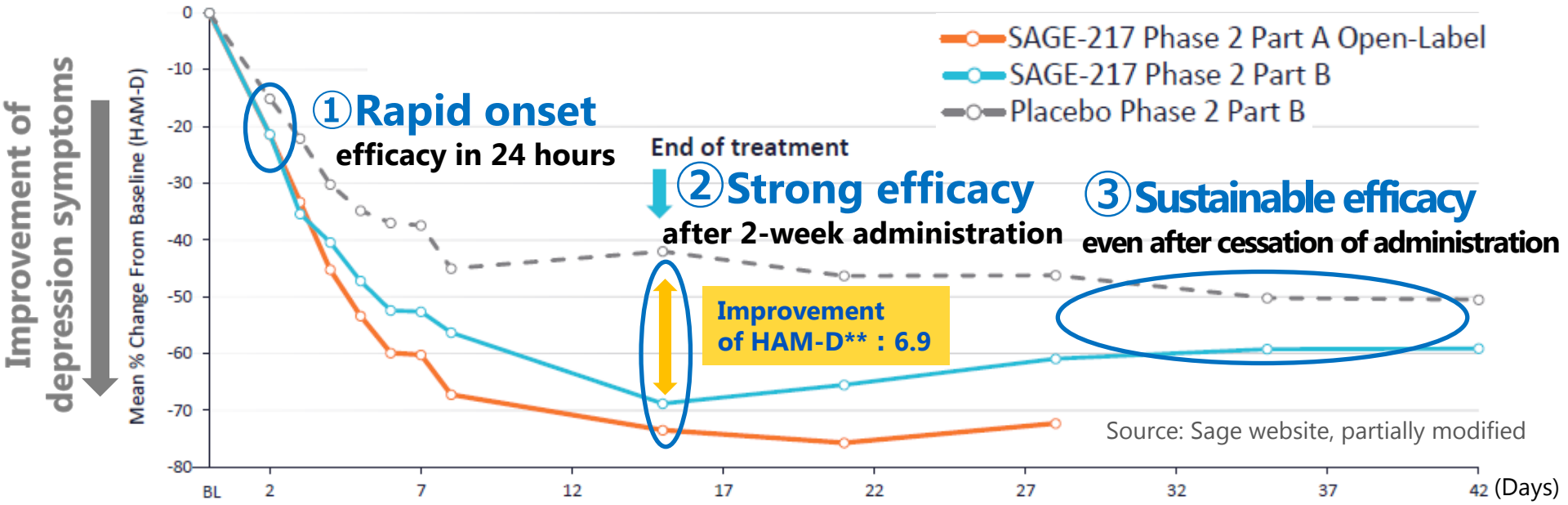
SHIONOGI

*1 WHO: Global Tuberculosis Report 2017
*2 IQVIA Analytics Link (J4A)
*5 Epi data, company data etc.
*3 Partnership on developing medicines with support from Bill & Melinda Gates Foundation
*4 Organization to advance development of new drugs for infectious diseases in the developing countries



SAGE：Novel Antidepressant S-812217

- A potential paradigm shift in the treatment of depression through **a novel mechanism*** affecting inhibitory neurons
- FDA designated **Break-Through Therapy** in US
- **Positive placebo-controlled Phase 2 Results** demonstrate potential in depressive disorders (figure)
- Plan to start of a clinical study in Japan in CY2018



- **Novel antidepressant following Cymbalta®**
- **Launching new development products in CNS field contributing to sales beyond 2020**

SHIONOGI

* $GABA_A$ positive allosteric modulator
** HAM-D: a way of determining a patient's level of depression

Xofluza™
~Top-Line Results of Global Phase III Study (HR* study)~

HR* Study
(CAPSTONE-2)

- High-risk patients aged ≧12 years
- 0-48 hours from onset
- Japan/US/EU/ Asia/Southern Hemisphere
- N=2,184

→ Randomization

- Xofluza™ 40 mg or 80 mg, single dose (80 mg, body weight≧80 kg)
- Placebo
- Oseltamivir 75 mg, twice daily for 5 days

Primary endpoint:
- Time to improvement of influenza symptoms

Key secondary endpoints:
- Anti-viral effects (viral titers**, duration of viral shedding***)
- Incidence of influenza-related complications

* HR: High risk（patients at high risk for influenza-related complications）

** Index of the amount of infectious virus in the body

*** Time that infectious virus is released from the body

Top-Line Results of HR Study

Achieved Primary Objective

Xofluza™ is the first medicine ever to demonstrate superior efficacy in high-risk patients in time to improvement of influenza symptoms compared with placebo in a clinical study

- **Primary endpoint: Superior efficacy in time to improvement of influenza symptoms compared with placebo**
- **Key secondary endpoints:**
  - **Superior anti-viral effects compared with placebo and with oseltamivir**
    - > Viral titers*
    - > Duration of viral shedding**
  - **Reduced the incidence of influenza-related complications compared with placebo**
- **Safety**
  - Well-tolerated
  - No new safety signals

Details to be presented at upcoming medical meetings

Valuable results to show the great efficacy and safety profile of Xofluza™ following the OwH* study**

Primary objective: superior efficacy compared with placebo in time to improvement of influenza symptoms

* Index of the amount of infectious virus in the body

** Time that infectious virus is released from the body

*** OwH: otherwise healthy

Progress in 1Q FY2018* (Pipeline)

Phase I	Phase II	Phase III	Submission	Approval, Launch

Global

Xofluza™

- **US NDA submission** (PDUFA date 2018/12/24)
- **HR study top-line results**
- **Taiwan NDA submission**

In Japan

S-005151

- Start of PhI study (Acute ischemic stroke)

S-600918

- Start of PhII study (Refractory/unexpected chronic cough)

OxyContin®TR

- Start of PhIII study (Chronic pain)

Xofluza®

- NDA submission (granule product)

Brightpoc® Flu·Neo

- Approval, Launch

SR-0379

- Start of PhII study (Cutaneous ulcer)

Out-licensed

DTG+3TC

- PhIII study top-line results (GEMINI)

Juluca®(DTG/RPV)

- Approval, Launch

Infectious diseases
Pain/CNS
Frontier

*Progress from April 1 to July 30, 2018
DTG: dolutegravir RPV: rilpivirine

Appendix

- Progress in 1Q FY2018 (Other Aspects) -
- Target Milestones for FY2018 -
- Progress of Pipeline -
- Revised Full Year Forecasts -
- Strategic Investment -
- Drug Discovery Strategies for Infectious Diseases -

Progress in 1Q FY2018* (Other Aspects)

- **May**
  - Collaboration with Aichi Prefecture for “Prevention of Drug Abuse”
  - Collaboration with Iwate Prefecture in “Support for Children’s Bright Future”
  - Started Shionogi’s internal use of PDPS**, a drug discovery platform developed by PeptiDream
  - Entered into a collaborative licensing, research and development program with Hsiri to discover and develop drugs for mycobacterial diseases
- **June**
  - Collaboration with SAGE to develop and commercialize S-812217
  - Investment in the clinical development of Nemesis “Symbiotics©”
  - Entered into a capital alliance between Shionogi Healthcare and Rohto
- **July**
  - Terminated the prior alliance with Purdue for the co-commercialization of Symproic® in the US (Shionogi has regained full rights to Symproic®)

* Progress from May 10 to July 30, 2018

** PDPS (Peptide Discovery Platform System) : Technology to obtain the peptide with high activity and high selectivity

Target Milestones for FY2018 : Approvals and NDA Submission

Product (indication)	Phase I	Phase II	Phase III	NDA submission	Approval
Mulpleta® (Thrombocytopenia associated with chronic liver disease)				**US (2017.12) EU (2018.1)**	US
Rizmoic® (Opioid-induced constipation)				**EU (2017.3)**	EU
Lisdexamfetamine (ADHD [pediatric])				**Japan (2017.4)**	Japan
Xofluza™ (Influenza virus infection)		**Achieved**	Global: ongoing	**US**	US
Xofluza™, granule (Influenza virus infection)		**Achieved (Apr. 2018)**	Japan: ongoing	Japan	
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections)			Global: ongoing	US	
Intuniv® (ADHD [adult])			Japan: Extension study, ongoing	Japan	

Target Milestones for FY2018 : Phase I ~ III

Product (indication)	Phase I	Phase II	Phase III	NDA submission	Approval
Xofluza® (Influenza virus infection [prophylaxis])			Japan: initiated		
OxyContin®TR (Treatment of moderate to severe chronic pain)			Japan: initiated	Achieved	
S-120083 (Inflammatory pain)		US: completed			
S-588410 (Bladder cancer)		Japan, EU: completed			
S-600918 (Refractory/unexpected chronic cough, Neuropathic pain)		Japan: initiated	Achieved (Refractory/unexpected chronic cough)		
S-770108 (Idiopathic pulmonary fibrosis)	Japan: completed				
S-637880 (Neuropathic pain)	Japan: completed				
S-005151 (Acute ischemic stroke)	Japan: initiated				
S-004992 (Tuberculosis)	Asia (China) : initiated	Achieved			

Pipeline -Developed by Shionogi (as of July 2018)

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Preclinical	Phase I	Phase II	Phase III	Filed
Influenza virus infection	**Global**			
HIV virus infection	**S-004992*** Tuberculosis	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Xofluza™ (US, Taiwan)** Influenza virus infection
Bacterial infection	**S-117957** Insomnia	**S-120083** Inflammatory pain		**Rizmoic® (EU)** Opioid-induced constipation
Bacterial infection	**S-237648** Obesity	**S-707106** Type2 diabetes		**Mulpleta® (US)** Thrombocytopenia
Mycobacterium disease		**S-488210** Head and neck squamous cell carcinoma		**Mulpleta® (EU)** Thrombocytopenia
Fungus infection		**epertinib** Malignant tumor		
Fungus infection		**S-588410** Bladder cancer		
Peptide	**In Japan**			
Vaccine for prevention	**S-812217*** Depression	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Xofluza®** Influenza virus infection (oral, granule)
ADHD	**S-600918** Neuropathic pain	**S-600918** Refractory/unexpected chronic cough	**Intuniv®** ADHD (adult)	**Oxycodone** Moderate to severe chronic pain
Opioid	**S-637880** Neuropathic pain	**S-237648** Obesity	**Cymbalta®** Depression (pediatric)	**Lisdexamfetamine** ADHD (pediatric)
Peptide	**S-010887** Neuropathic pain	**S-525606** Allergic rhinitis caused by Japanese cedar allergen	**S-588410** Esophageal cancer	
Alzheimer's disease	**S-770108** Idiopathic pulmonary fibrosis	**S-588410** Bladder cancer	**Oxycodone** Moderate to severe chronic pain	
Post-stroke spasticity	**S-005151** Acute ischemic stroke	**SR-0379** Cutaneous ulcer		
Diabetes				
Obesity				
Hypertrophic scars				
Cancer metastasis				
Adjuvant				
Peptide				

- Infectious diseases
- Pain/CNS
- Other

Progress from May 10 to July 30, 2018

*In preparation for Phase 1

Pipeline -Out-licensed (as of July 2018)

Preclinical	Phase I	Phase II	Phase III	Filed
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		**DTG+3TC** Treatment for HIV infection GEMINI study (untreated) TANGO study (maintenance)	**Osphena®** Vaginal dryness associated with postmenopausal VVA
			CAB LAP Prevention for HIV infection	
			CAB+RPV LAP Treatment for HIV infection	

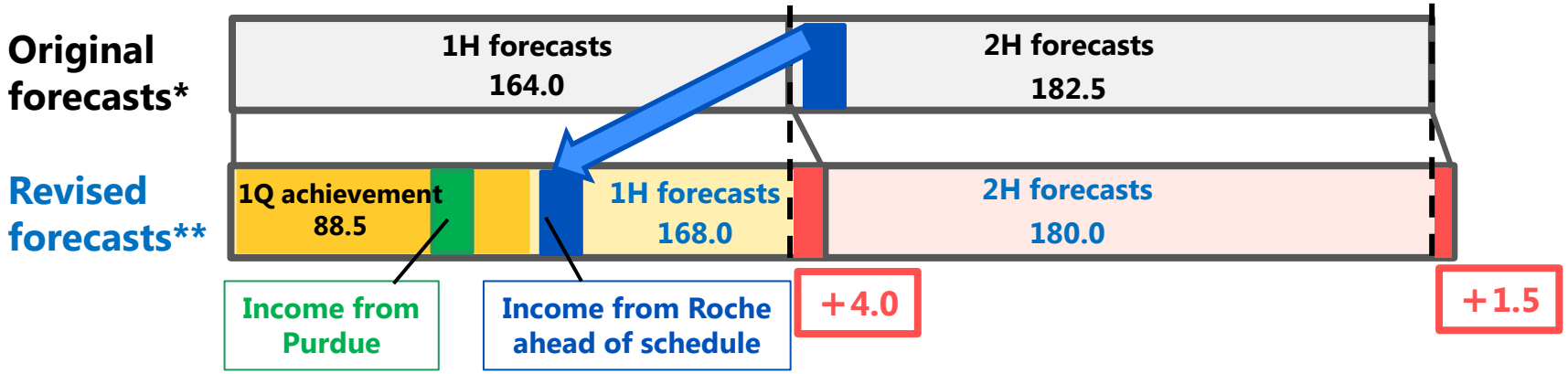
- **Infectious diseases**
- **Pain/CNS**
- **Others**

DTG: dolutegravir 3TC: Lamivudine RPV: rilpivirine CAB：cabotegravir

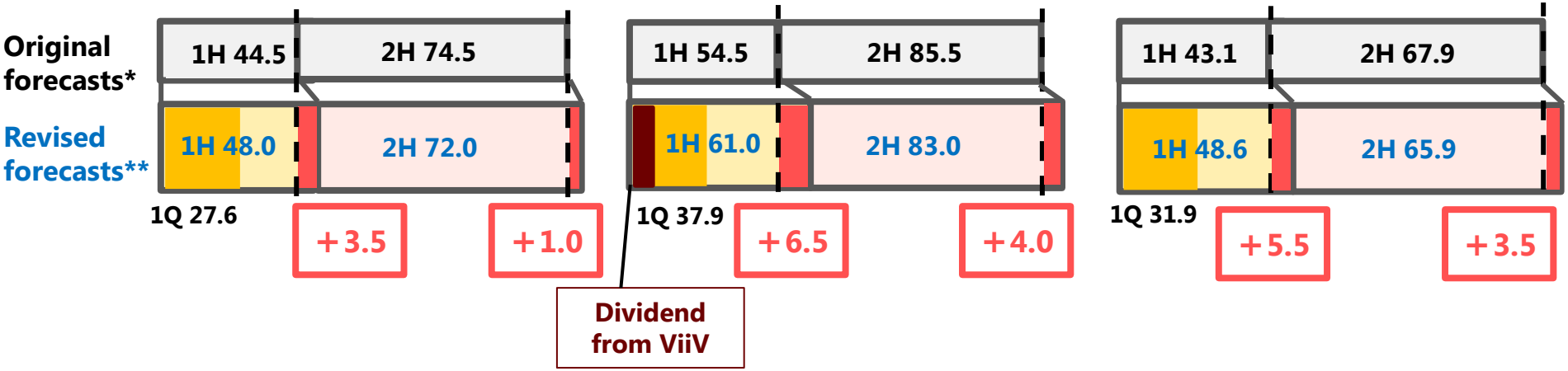
Revised Full Year Forecasts

- **Sales（346.5→348.0）**

(Unit: B yen)



- **Operating income (119.0→120.0)**
- **Ordinary income (140.0→144.0)**
- **Profit attributable to owners of parent (111.0→114.5)**



* Forecasts announced on May 9, 2018
** Forecasts announced on July 23, 2018

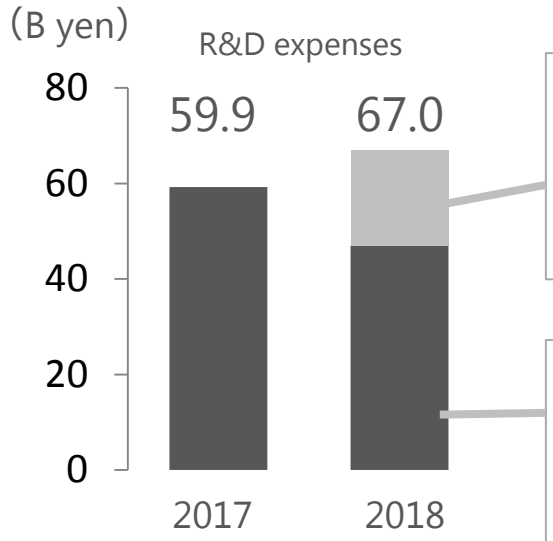
Announced in FY2017 Financial Results

Strategic Investment for Sustainable Growth

Development of Xofluza™ is in its final stage

Favorable opportunity to invest in other growth drivers

New investment to expand pipeline for sustainable growth



Strategic Investment (ca. 20 B yen)
New investment to **expand pipeline for launches beyond 2020** and to **introduce new technologies**

Focus resources on the 7 high-priority projects* by strengthening total cost management, although ordinary R&D expenses will be lower than in FY2017

Strategic investment (ca. 20 B yen) in R&D is planned for sustainable growth

* Presentation Material of R&D Meeting on Mar 15, 2018 http://www.shionogi.co.jp/en/ir/pdf/e_p180315.pdf
1: Novel HIV drug, 2: Peptide drugs, 3: Adjuvant, 4: S-044992, 5: S-600918, 6: S-637880. 7: S-770108

Nemesis：Investment in Novel Technology for Antimicrobial Resistance (AMR)

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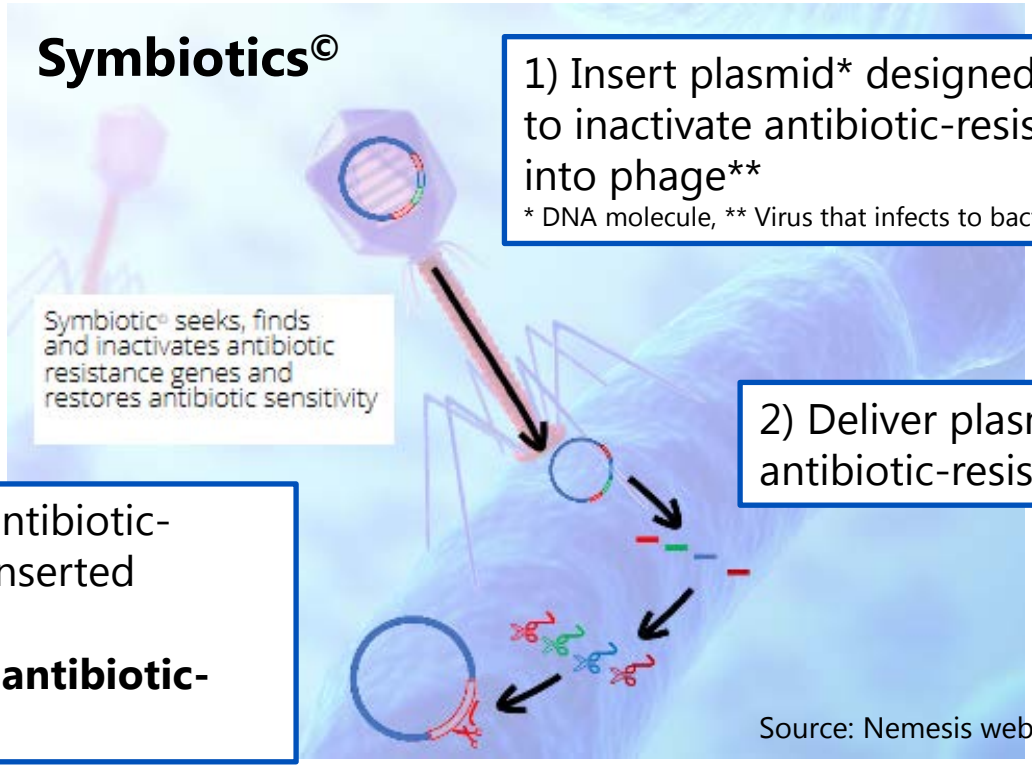
Acquire knowledges about the novel modality “Symbiotics©” an approach to the problem of AMR



1) Insert plasmid* designed specifically to inactivate antibiotic-resistant genes into phage**

* DNA molecule, ** Virus that infects to bacteria

2) Deliver plasmid into antibiotic-resistant bacteria

3) Modification of antibiotic-resistant genes by inserted plasmid

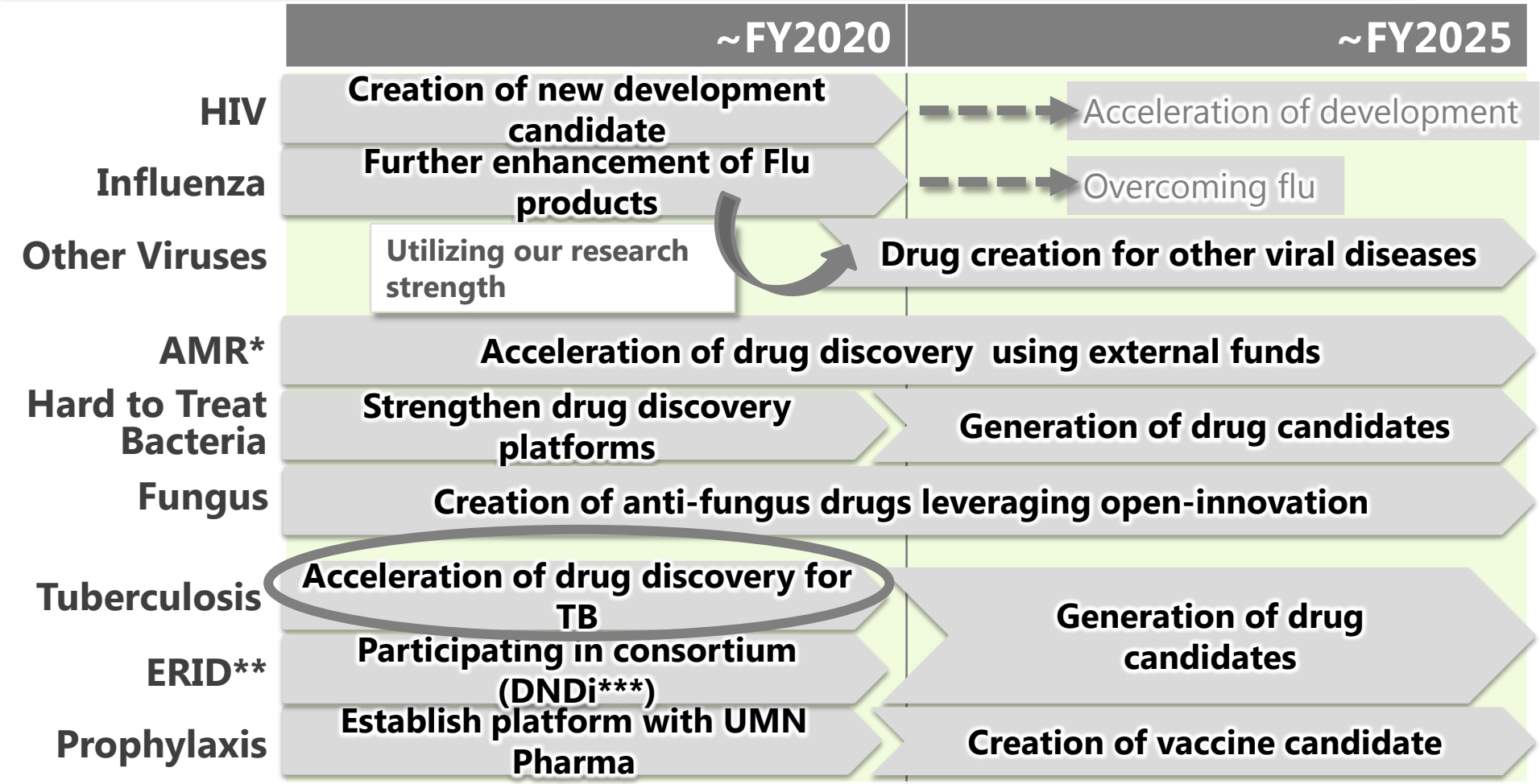
⇒ **Inactivation of antibiotic-resistant genes**

Source: Nemesis website, partially modified

Expanding therapeutic options to AMR as a leading company in the infectious disease field

Announced in FY2017 R&D Day

Drug Discovery Strategies for Infectious Diseases



Short term) Focusing on HIV, influenza and preparing for the future
Medium to long term) Expand/shift scope to include other viruses, **tuberculosis**

* AMR: Antimicrobial resistance
** ERID: Emerging and Re-emerging Infectious Diseases
*** DNDi: Drugs for Negrected Diseases initiative

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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