



3rd Quarter of Fiscal 2018 Financial Results

Conference Call

January 31, 2019



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1. Overview of Q3 FY2018 Financial Results

Financial Results (Consolidated)



(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Progress vs. forecasts	Apr.-Dec. Results	Change (%)	Change (B yen)
Sales	354.0	265.2	74.9%	263.4	0.7%	1.9
Operating income	124.5	97.4	78.3%	90.1	8.1%	7.3
Ordinary income	148.5	115.7	77.9%	105.5	9.7%	10.2
Profit attributable to owners of parent	118.5	94.3	79.6%	79.7	18.3%	14.6

<Sales and Each profit measure>

- Sales and each profit measure have progressed smoothly toward full-year forecasts
- Sales and each profit measure were higher than Apr.-Dec. FY2017

<Each profit measure>

- Apr.-Dec. results by every profit measure reached record-high levels
 - Operating income and profit attributable to owners of parent: 4 consecutive years
 - Ordinary income: 10 consecutive years

Exchange Rate (average)	FY2018 forecasts	FY2018 Apr.-Dec. results
USD (\$) – JPY (¥)	105.0	111.15
GBP (£) – JPY (¥)	145.0	146.34
EUR (€) – JPY (¥)	130.0	129.48

Statement of Income



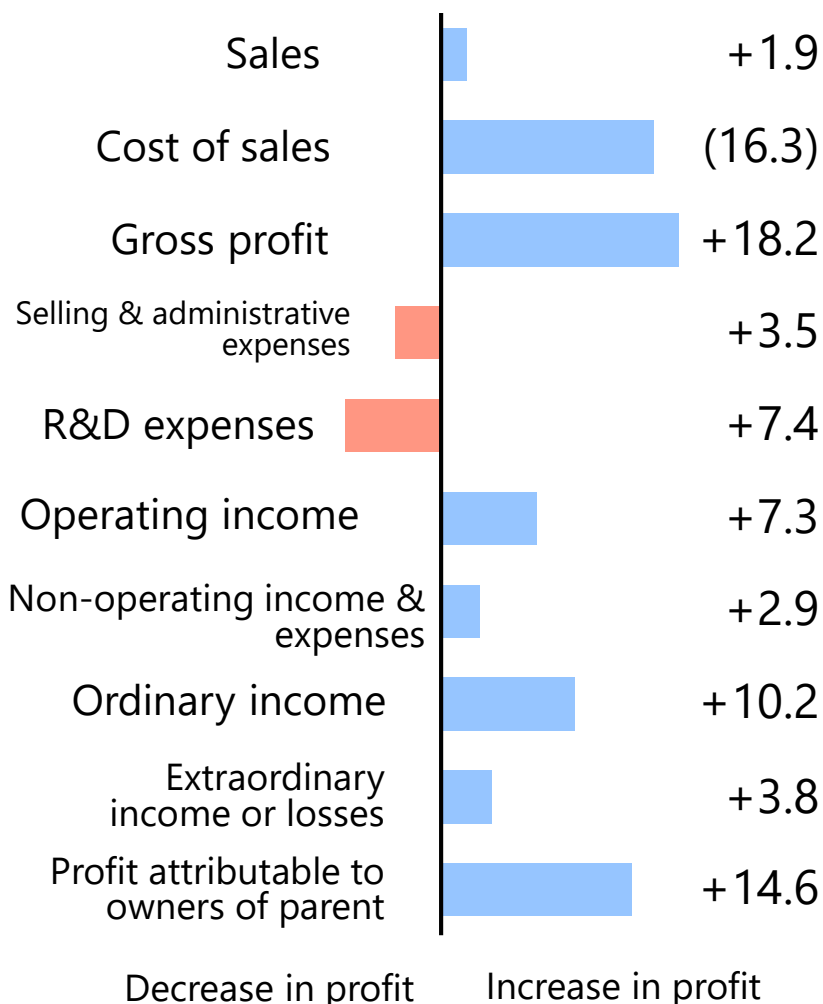
(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achieve- ment (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Sales	354.0	265.2	74.9	263.4	0.7	1.9
	16.1	15.2		21.5		
Cost of sales	57.0	40.4	70.8	56.7	(8.8)	(16.3)
Gross profit	297.0	224.9	75.7	206.6	8.8	18.2
SG&A expenses	48.7	48.0		44.2		
	172.5	127.4	73.9	116.5	9.4	10.9
Selling & administrative expenses	29.4	28.1		26.9		
	104.0	74.5	71.6	70.9	5.0	3.5
	19.4	20.0		17.3		
R&D expenses	68.5	53.0	77.3	45.6	16.2	7.4
Ordinary R&D expenses*	50.4	38.2	75.8	45.6	(16.2)	(7.4)
Strategic investment	18.1	14.8	81.8	-	-	14.8
	35.2	36.7		34.2		
Operating income	124.5	97.4	78.3	90.1	8.1	7.3
Non-operating income & expenses	24.0	18.2	75.9	15.3	18.8	2.9
	41.9	43.6		40.0		
Ordinary income	148.5	115.7	77.9	105.5	9.7	10.2
Profit attributable to owners of parent	118.5	94.3	79.6	79.7	18.3	14.6

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

• Y on Y comparison

(Unit: B yen)



Main Variation Factors in Oct.-Dec. (Y on Y)

- **Sales**
 - Income from Roche for the approval of Xofluza® in the U.S.
- **SG & A expenses**
 - R&D expenses: Strategic Investments
 - › Net increase of 1.7 B yen
- **Extraordinary income or losses**
 - Profit on sale of investment securities

Sales by Segment



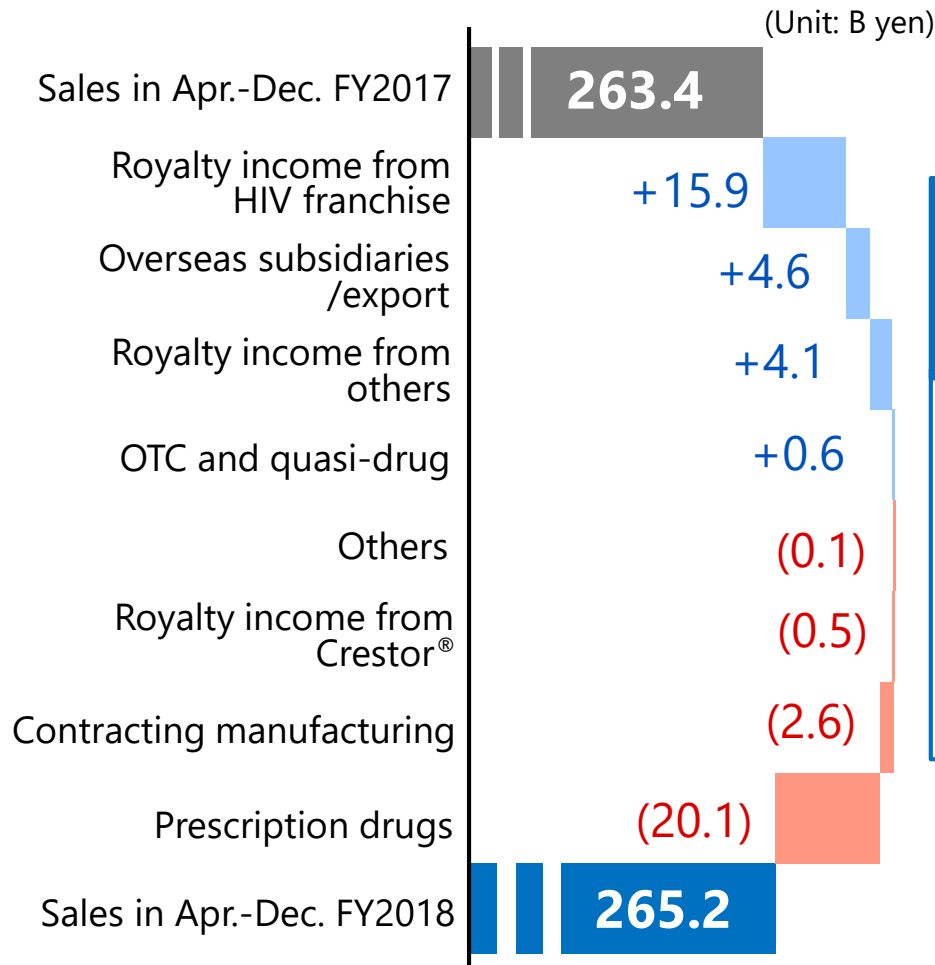
(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Prescription drugs	119.3	88.3	74.0	108.4	(18.5)	(20.1)
Overseas subsidiaries/export	31.3	22.1	70.6	17.5	26.6	4.6
Shionogi Inc.	12.4	9.4	75.6	8.4	12.0	1.0
Osphena [®]	4.1	2.4	58.4	3.0	(18.7)	(0.6)
C&O	12.4	8.2	66.1	4.8	71.3	3.4
Contract manufacturing	12.9	9.2	71.0	11.8	(22.1)	(2.6)
OTC and quasi-drug	7.4	6.3	85.5	5.7	10.2	0.6
Royalty income	180.6	137.5	76.1	118.1	16.4	19.4
HIV franchise	124.9	89.9	72.0	74.0	21.5	15.9
Crestor [®]	21.1	16.4	77.9	17.0	(3.2)	(0.5)
Others	34.6	31.2	90.0	27.1	15.1	4.1
Others	2.5	1.9	76.1	2.0	(4.5)	(0.1)
Total	354.0	265.2	74.9	263.4	0.7	1.9

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



• Y on Y comparison



Main Variation Factors Occurring in Oct.-Dec. (Y on Y)

(Apr.-Dec., Y on Y: +1.9 B yen, +0.7%)

- **Royalty income**
 - Income from Roche for the approval of Xofluza® in the U.S.
- **Prescription drugs**
 - Sales growth of Influenza family*

Sales of Prescription Drugs in Japan



(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achieve- ment (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Cymbalta [®]	26.0	18.6	71.6	18.2	1.9	0.4
Intuniv [®]	6.1	3.9	64.1	1.2	223.6	2.7
Xofluza [®]	13.0	9.9	76.4	-	-	9.9
Rapiacta [®]	1.1	0.77	68.4	1.2	(37.3)	(0.5)
Brightpoc [®] Flu	1.3	0.58	46.2	0.53	10.1	0.1
OxyContin [®] franchise	8.7	5.8	67.1	7.0	(16.9)	(1.2)
Symproic [®]	1.6	1.2	76.0	0.4	217.5	0.8
Total of strategic products	57.7	40.8	70.7	28.6	42.8	12.2
Actair [®]	0.18	0.14	78.7	0.09	57.6	0.1
Mulpleta [®]	0.19	0.13	65.3	0.13	0.3	0
Pirespa [®]	5.9	4.5	76.4	4.9	(9.1)	(0.4)
Total of new products	64.0	45.6	71.2	33.7	35.1	11.8
Crestor [®]	9.7	7.8	81.0	26.3	(70.2)	(18.5)
Irbetan [®] franchise	6.0	4.4	73.2	11.9	(63.0)	(7.5)
Others	39.6	30.5	76.9	36.5	(16.4)	(6.0)
Prescription drugs	119.3	88.3	74.0	108.4	(18.5)	(20.1)

2. Efforts and Progress in Q3 FY2018

Summary of Progress in Q3 FY2018



	Mid- to Long-term Plan	Major Progress
(1) Japanese Business	Rebuilding foundation to achieve greater strength in Japan	<p><Prescription drugs in Japan></p> <ul style="list-style-type: none"> Focus resources on new products <ul style="list-style-type: none"> Oct. to Dec. sales were increased from the previous year: 3.1 billion yen Increase in the ratio of strategic products: 39.2% in 1H, 55.5% in Q3
(2) Overseas Business	Strengthen presence in the U.S.	<p><U.S. Business></p> <ul style="list-style-type: none"> Cefiderocol: on track to meet our planned approval timelines Selling Symproic® and Mulpleta® ourselves
(3) R&D	Promote development of next growth drivers	<ul style="list-style-type: none"> Steady progress of 8 high-priority projects* Favorable progress of HIV drugs Four new business alliance agreements <ul style="list-style-type: none"> Vast, Ube, Tetra, PeptiDream

Achieve increases in sales and profits in FY2018 and further growth in FY2019 while maintaining continuous investment for the next stage

(1) Japanese Business: Driving Sales Growth by Our Own Earning Power



Sales of prescription drugs in Japan (Y on Y comparison)

The impact of share capture
by generic competitors
hit a plateau in 1H FY2018



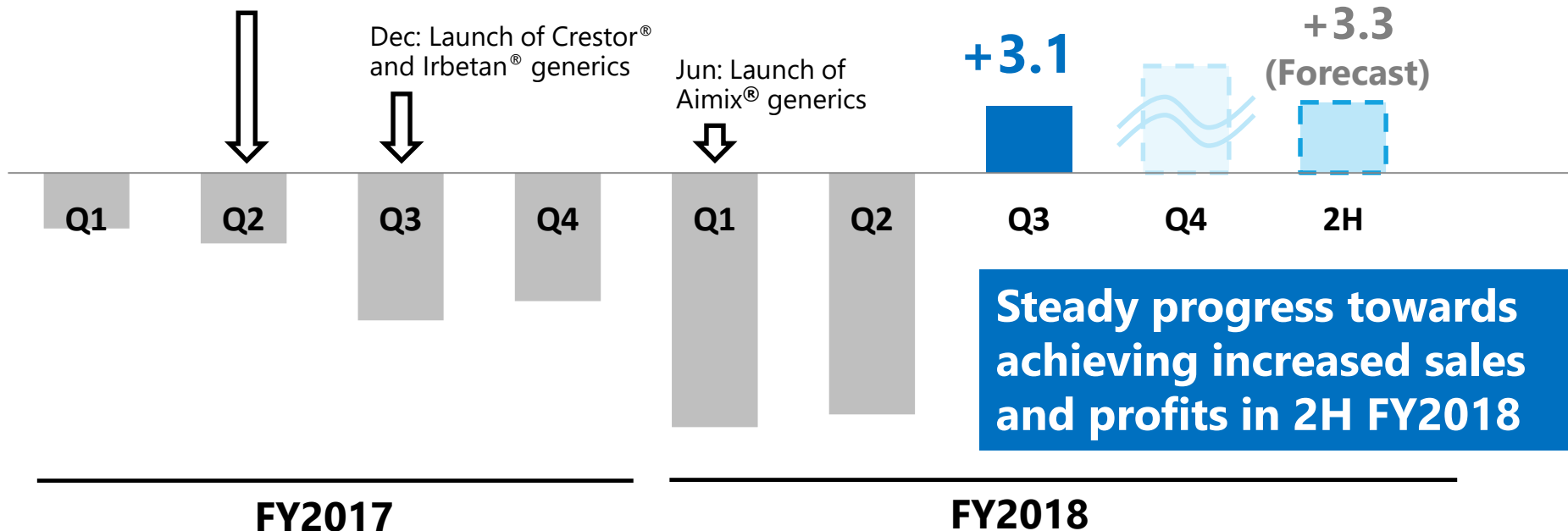
Sales-growth phase by
our own earning power

Sep: Launch of Crestor®
authorized generic

Dec: Launch of Crestor®
and Irbetan® generics

Jun: Launch of
Aimix® generics

(Unit: B yen)



(1) Japanese Business: Driving Sales Growth by Our Own Earning Power



Cymbalta®

- Prescriptions increased (15% or more increase from the previous year)
- Increase primarily in the pain area
 - Prescription increase in the orthopedic market
 - 29% or more increase from the previous year

Intuniv®

- Sales increase from the previous year (ca. 3.2-fold vs Oct.-Dec. FY2017)
- Top share in the non-stimulant market for pediatric ADHD for naïve and switch patients and add-on treatment*
- Advancing development to maximize the value of each product:
 - Under review by PMDA: Intuniv® (adult), lisdexamfetamine (pediatric)

Influenza family**

- Rapid sales increase due to seasonal flu outbreak
- Positive societal attention and recognition
- Clinical studies of Xofluza® are proceeding well to maximize its value

Opioid family***

- OxyContin® franchise:
 - Switching to OxyContin® TR
- Symproic®:
 - Sales increase from the previous year (ca. 3.2-fold vs Oct.-Dec. FY2017)

Sales increase driven by new sales organization and by focusing resources on strategic products

* Based on prescription volume in Nov. 2018 ** Xofluza®, Rapiacta®, Brightpoc® Flu, Brightpoc® Flu•Neo

*** OxyContin®, OxyContin® TR, OxiNorm®, OxiFast®, Methapain®, Symproic®

Positive societal attention and recognition

- Profile which can change treatment of influenza
 - Single-dose, oral therapy
 - Rapid viral decrease in the body
- Positive reputation with medical experts and patients
- Coverage in various media (TV, newspaper, internet, radio, magazine etc.)

Japan

- **Providing information to physicians in an efficient and effective manner**
 - Suitable promotion in each region and usage of e-detail
- **Steady progress of two Phase 3 clinical trials (prophylaxis, new dosage for children)**

Global (the Roche Group)

- **Launched in the U.S.: middle of Nov. 2018**
 - Ongoing active promotion by the Roche group heading into the peak full season
Sales so far: ca. 1.4 B yen (CHF 13M)
- **Steady progress of global development**
 - Steady progress of global clinical trials in pediatric and severely ill hospitalized patients

(2) Business in the U.S.



Infectious disease

- **Cefiderocol: On track to meet our planned approval timelines**
 - Steady progress of Phase III studies (CR*, HAP/VAP/HCAP**)

Pain/CNS

- **Symproic®: Sustained by our own promotion**
 - Efficient promotion by contract sales reps, Keep market exploited by Purdue
 - Selection of a new business partner is ongoing

Frontier

- **Mulpleta®: Initiated full-scale promotion in Dec.**
 - Patient access and uptake supported by "Mulpleta Assist" program
 - Tightly focused sales effort
- **Osphena®: Continue to support our collaborator, Duchesnay**
 - > Supplemental indication "moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy": approved in Jan. 2019

Steady progress toward breakeven in FY2018 and building our foundation for expanding U.S. business

(3) R&D- Progress of Next Growth Drivers



		Pipeline	Progress in Q3 FY2018
Infectious disease	In house	Novel HIV drug	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
		S-004992 (Tuberculosis)	Non-clinical studies are progressing to support initiation of Phase I study (China)
Pain/CNS	In house	S-600918 (Refractory/unexplained chronic cough, Neuropathic pain)	Proof of concept (Phase II) study (Refractory/unexplained chronic cough, Japan) is progressing ⇒Top-line results are anticipated in FY2018
		S-637880 (Neuropathic pain)	Phase I study and micro-dose study (Japan) are progressing Micro-dose studies: study 1, only PET* probe is administered; study 2, PET probe and S-637880 are administered
	Collabo-ration	S-812217 (Depression)	Phase I study (Japan) was initiated in Oct. 2018
Others	In house	Adjuvant	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
		S-770108 (Idiopathic pulmonary fibrosis)	Phase I study (Japan) was completed
	Collabo-ration	Peptide	Optimization of HIT peptides to initiate new drug discovery projects

Steady progress of 8 high-priority projects

→Details will be explained in the R&D Day scheduled for Mar. 14, 2019

S-812217: Novel Antidepressant



Novel mechanism that differs from those of existing antidepressants

GABA_A Positive Allosteric Modulator (PAM)

- Existing antidepressant: **Activate suppressed neural activity**
 - Increase of monoamine
- S-812217: **Suppress excessive neural activity**
 - Activate inhibitory neurons
 - Expected rapid onset of efficacy due to direct effect on inhibitory neurons

S-812217 binding site
= Neuroactive steroid site



Extrasynaptic GABA_A receptor

Steady progress of SAGE pipelines

- SAGE-217 (S-812217)**
 - SAGE-217 met primary and secondary endpoints in Phase III clinical trial for "postpartum depression"
 - Phase III clinical trial for "major depression disorder" is proceeding
- Injectable GABA_A PAM ZULRESSO™ (brexanolone)**
 - Under review by FDA for "postpartum depression"
 - FDA Advisory Committee voted 17-1 in support of benefit-risk profile
 - PDUFA date*: Mar. 19, 2019

Expected to be a novel antidepressant that can change existing treatment
(The presentation meeting will be held on Feb. 5, 2019 with SAGE)

(3) R&D DTG/CAB Franchise - HIV Treatment Platform



Tivicay[®], Triumeq[®] Launch: 2013~

- **Key drug for 3-drug regimen**

Juluca[®] (DTG/RPV) Launch: 2017~

- **First 2-drug regimen for maintenance therapy**
- Nov. 2017-Jun. 2018: Approved in US, EU, CAN, AUS

Dec. 2018: Launched in Japan

DTG/3TC Launch: 2019~

- **First 2-drug regimen for naïve patients**
- Sep. 2018: MAA submission in EU, Oct. 2018: NDA submission in US (naïve patients)
 - PDUFA action date is anticipated in 6 months (priority review voucher)

CAB+RPV Launch: 2019~

- **First long acting injection** (monthly or bimonthly)
- Aug. 2018: positive results from ATLAS.

Oct. 2018: positive results from FLAIR

- 1H 2019: NDA/MAA submission in US and EU (monthly injection)





CAB prophylaxis Launch: 2021~

- **First long-acting injectable for prophylaxis** (bimonthly injection)

Continued excellent progress in expanding the platform and its value

Progress of Strategic Investment



- **Dec. 6, 2018 Investment in Vast** 
 - Investment in **Nitric Oxide Inhaled Antimicrobial Drug Platform**
 - > Obtained preferential right of negotiation for future in-license of the leading compound and subsequent compounds
- **Dec. 10, 2018 Collaboration with Ube** 
 - Collaborative research for **novel anti-RS (respiratory syncytial) virus drug candidates**
 - > Accelerate development of anti-RS virus drugs through a synergistic joint SAR effort in collaboration with Ube
- **Dec. 19, 2018 In-licensing from Tetra** 
 - **In-licensing of BPN14770, a drug candidate for cognitive and memory deficits**
 - > Obtained development, manufacturing, and marketing rights to BPN14770 in Japan, Taiwan and Korea
- **Jan. 23, 2019 Collaboration with PeptiDream** 
 - **Novel technology which enables compounds to be selectively delivered into the brain**
 - > Collaborative research on Peptide Drug Conjugates (PDC)

4. Shareholder Return

Share Buyback and Cancellation

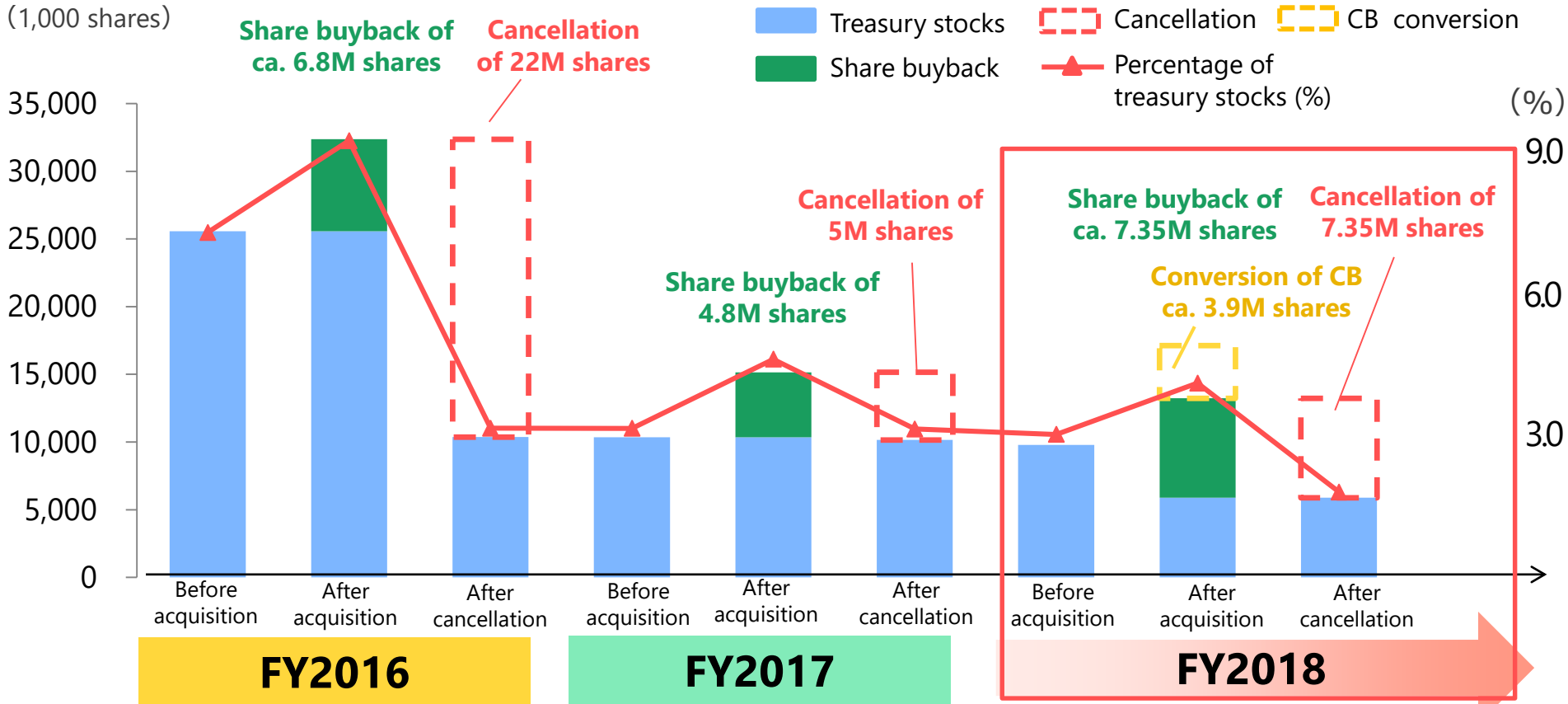
Share buyback

- Share buyback: 7,350,400 shares
- Total amount of buyback: 49,999,850,123 yen
- Period: Jul. 31, 2018~Dec.18, 2018

Cancellation of treasury shares

- Total shares to be cancelled: 7.35M shares (planned)
- Date for cancellation: Feb. 20, 2019

(1,000 shares)



Appendix

- Major Progress in Q3 FY2018
- Target Milestones for FY2018
- Progress of Pipeline
- Launch Plan
- Business Plan for 2H FY2018
- Strategic Investment

Major Progress in Q3 FY2018* (Pipeline)



Global

S-588210

- Start of PhI Study

Naldemedine
(Rizmoic®)

- Recommendation from CHMP

Lusutrombopag

- Recommendation from CHMP

In Japan

S-812217

- Start of PhI Study

S-770108

- Completion of PhI Study

Xofluza®

- Start of PhIII Study
(New dosage for children)

CAB+RPV

- PhIII study
top-line results
(FLAIR)

Xofluza™

- Launch (U.S.)

Juluca® (DTG/RPV)

- Approval, Launch (Japan)

Osphena®

- Approval (U.S.) (Dryness)

Out-licensed

Infectious
diseases

Pain/CNS

Frontier

Major Progress in Q3 FY2018* (Others)



- **Dec.**

- Investment in Vast Therapeutics with preferential right of negotiation for future in-license of Nitric Oxide inhaled antimicrobial drug candidates
- Collaborative research with Ube Industries for novel anti-RS virus drug candidates
- Collaboration with Tetra Discovery Partners on development and commercialization of BPN14770, a candidate drug for cognitive and memory deficits

- **Jan.**

- Collaborative research with PeptiDream for new peptide drug conjugate (PDC) Discovery

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)			Achieved (U.S., Aug.)	US (2017.12) EU (2018.1)	US
Naldemedine (Rizmoic®) (Opioid-induced constipation)				EU (2017.3)	EU
Lisdexamfetamine (ADHD [pediatric])				Japan (2017.4)	Japan
Xofluza™ (Influenza virus infection)		Achieved (Oct.)	Global: ongoing	US (2018.4)	US
Xofluza™, granule (Influenza virus infection)		Achieved (Sep.)	Japan: ongoing	Japan	Japan
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections)			Global: ongoing	US	
Intuniv® (ADHD [adult])			Achieved (Aug.)	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	Achieved (Q2)	
OxyContin®TR (Treatment of moderate to severe chronic pain)			Japan: initiated	Achieved (Q1)	
S-120083 (Inflammatory pain)		US: completed		Achieved (Q3)	
S-588410 (Bladder cancer)		Japan, EU: completed			
S-600918 (Refractory/unexpected chronic cough, Neuropathic pain)		Japan: initiated		Achieved (Q1) (Refractory/unexplained chronic cough)	
S-770108 (Idiopathic pulmonary fibrosis)	Japan: completed			Achieved (Q3)	
S-637880 (Neuropathic pain)	Japan: completed				
S-005151 (Acute ischemic stroke)	Japan: initiated			Achieved (Q1)	
S-004992 (Tuberculosis)	Asia (China): initiated				

Pipeline (as of Jan. 31, 2019)



Preclinical	Phase I	Phase II	Phase III	Filed
Influenza virus infection HIV virus infection Bacterial infection Bacterial infection Mycobacterium disease Fungus infection Fungus infection Peptide Vaccine for prevention ADHD Opioid Peptide Alzheimer's disease Cognitive and memory deficits Post-stroke spasticity Obesity NASH Cancer metastasis Adjuvant Peptide	Global S-004992* Tuberculosis S-117957 Insomnia S-237648 Obesity S-588210 Solid tumor In Japan S-812217 Depression S-600918 Neuropathic pain S-637880 Neuropathic pain S-010887 Neuropathic pain S-005151 Acute ischemic stroke S-770108 Idiopathic pulmonary fibrosis	Cefiderocol Multidrug-resistant Gram-negative bacterial infections S-120083 Inflammatory pain S-707106 Type2 diabetes S-488210 Head and neck squamous cell carcinoma epertinib Malignant tumor S-588410 Bladder cancer Cefiderocol Multidrug-resistant Gram-negative bacterial infections S-600918 Refractory/unexpected chronic cough S-237648 Obesity S-525606 Allergic rhinitis caused by Japanese cedar allergen S-588410 Bladder cancer SR-0379 Cutaneous ulcer ADR-001** Decompensated liver cirrhosis	Cefiderocol Multidrug-resistant Gram-negative bacterial infections Cefiderocol Multidrug-resistant Gram-negative bacterial infections Xofluza™ Influenza virus infection (prophylaxis) Xofluza™ Influenza virus infection (New dosage for children) Cymbalta® Depression (pediatric) Oxycodone Moderate to severe chronic pain S-588410 Esophageal cancer	Baloxavir Marboxil (Taiwan) Influenza virus infection Naldemedine (Rizmoic®) (EU) Opioid-induced constipation Lusutrombopag (EU) Thrombocytopenia Oxycodone Moderate to severe chronic pain Lisdexamfetamine ADHD (pediatric) Intuniv® ADHD (adult) • Infectious diseases • Pain/CNS • Other

Pipeline -Out-licensed (as of Jan. 31, 2019)



Preclinical	Phase I	Phase II	Phase III	Filed
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		DTG/3TC Treatment for HIV infection TANGO study (maintenance)	DTG/3TC (EU/US) Treatment for HIV infection
			CAB LAP Prevention for HIV infection	
			CAB+RPV LAP Treatment for HIV infection	
			Xofluza™ Severe influenza virus infection	
			Xofluza™ Influenza virus infection (pediatric)	<ul style="list-style-type: none"> • Infectious diseases • Pain/CNS • Others

Target Milestones for Launch of Products



FY2017 (Achieved)	FY2018	FY2019
In Japan		
Symproic® Intuniv® ADHD (pediatric) Oxycodone Tamper resistant formulation Actair® Pediatric allergic rhinitis caused by house-dust mite allergen Xofluza® (adult, pediatric)		Intuniv® ADHD (adult) Lisdexamfetamine ADHD (pediatric) Xofluza® (granule)
Global		
Symproic® (US)	Mulpleta® (US) Launched Rizmoic® (EU)	Cefiderocol (US) Lusutrombopag (EU) Baloxavir marboxil (Taiwan)
Out-licensed		
Juluca® (DTG/RPV)(US)	Juluca® (DTG/RPV) (EU) Osphena® (US) Launched Vaginal dryness associated with postmenopausal VVA Launched Xofluza™ (US, OwH*) Launched	DTG/3TC (US, EU) CAB+RPV (US) Xofluza™ (US, HR**)

Efforts in 2H FY2018 – in Mid- to Long-term Plan



(1) Japanese Business

Rebuilding foundation to achieve greater strength in Japan (P.27-30)

- New approach to expand sales of new products, such as Cymbalta[®], Intuniv[®], and Xofluza[®]

(2) Overseas Business

Strengthen presence in the U.S. (P.31)

- Improve efficiency by combining partnering and our own promotion
- Intensive investment of resources in the hospital/specialty market

(3) R&D

Promote development of the next growth drivers (P.32-35)

- Intensive investment of capital in high-priority projects
- Expanding range of treatment options in the HIV franchise that supports earnings base

Japanese Business: Driving Sales Growth by Our Own Earning Power



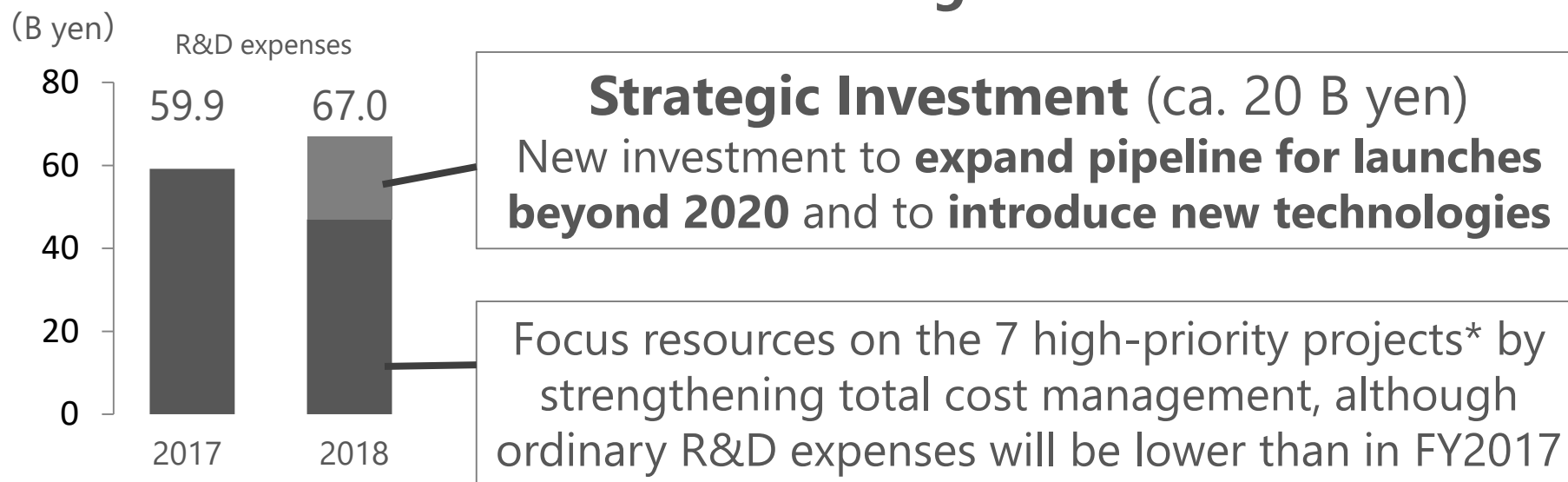
(Unit: B yen)

Prescription Drugs in Japan	2H FY2017 Results	2H FY2018 Forecasts (Revised on Oct. 29)	Oct.-Dec. FY2017 Results	Oct.-Dec. FY2018 Results	Y on Y comparison	
					2H Forecasts (Revised on Oct. 29)	Oct.-Dec. Results
New products (including strategic products)	27.7	41.4	13.1	23.0	+13.7	+9.8
Crestor®, Irbetan® franchise	14.1	7.4	8.4	4.0	(6.7)	(4.4)
Others	24.2	20.5	13.6	11.4	(3.7)	(2.3)
Total	66.0	69.3	35.2	38.3	+3.3	+3.1

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) in R&D
is planned for sustainable growth**

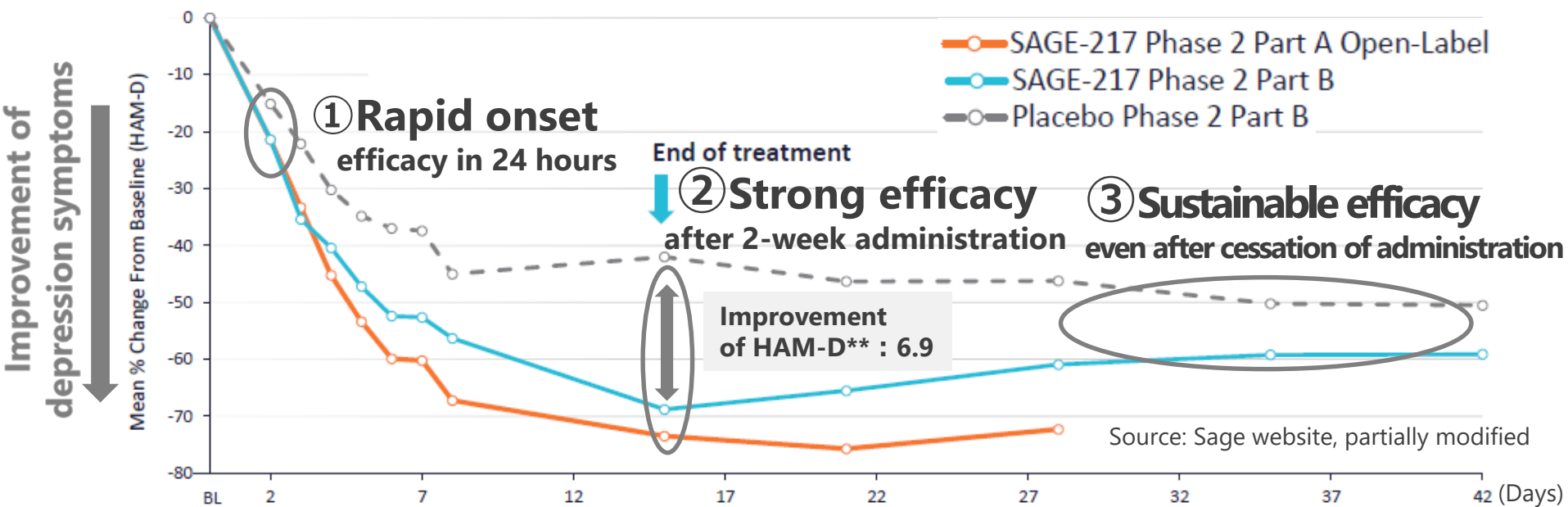


- **Novel mechanism of action**, efficacy on both tuberculosis and non-tuberculosis mycobacterial disease, potential to fulfill unmet medical needs
- Start R&D for the treatment of NTM Disease

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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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

- 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

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

Symbiotics[©]

Symbiotic[®] seeks, finds and inactivates antibiotic resistance genes and restores antibiotic sensitivity

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

Regenerative Medicine Product Candidate: ADR-001

- “Cellular-based products” prepared from mesenchymal stromal cells (MSC) derived from allogeneic adipose tissue by Rohto’s original technology
 - Rohto is conducting Phase I/II study in patients with decompensated liver cirrhosis
-
- **Expected to reduce fibrosis** through the effect of cytokines secreted from stromal cells
 - Prospect for **stable supply**
 - Prospect for supply at an affordable price compared to treatment with iPS cells or ES cells



**Improve QOL of patients with decompensated liver cirrhosis,
for which there is no effective treatment**



SHIONOGI

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**Expand our therapeutic modalities looking ahead to
Beyond 2020 by reinforcing our drug discovery platform
in the regenerative medicine area**

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- 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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