

3rd Quarter of Fiscal 2017 Financial Results

Conference Call

February 5, 2018

SHIONOGI

Financial Results (Consolidated)

(Unit B yen)

	FY2017			FY2016	YonY	
	Full year forecasts	Apr.-Dec. results	Progress vs. forecasts (%)	Apr.-Dec. results	change (%)	change (B yen)
Sales	**345.0**	**263.4**	**76.3%**	256.5	**2.7%**	**6.8**
Operating income	**113.5**	**90.1**	**79.4%**	87.7	**2.7%**	**2.4**
Ordinary income	**132.0**	**105.5**	**79.9%**	91.0	**15.9%**	**14.5**
Profit attributable to owners of parent	**101.0**	**79.7**	**78.9%**	67.5	**18.0%**	**12.2**

- **Good business progress vs. forecasts**
- **Operating income and profit attributable to owners of parent**
  - Higher than the levels in Apr.-Dec. of any prior fiscal year for three consecutive years
- **Ordinary income**
  - Higher than the levels in Apr.-Dec. of any prior fiscal year for nine consecutive years

Exchange rate (average)	FY2017 forecasts	FY2017 Apr.-Dec. results
USD ($) – JPY (¥)	**110**	**111.70**
GBP (£) – JPY (¥)	**140**	**145.74**
EUR (€) – JPY (¥)	**120**	**128.57**

Statements of Income (Consolidated)

(Unit B yen)

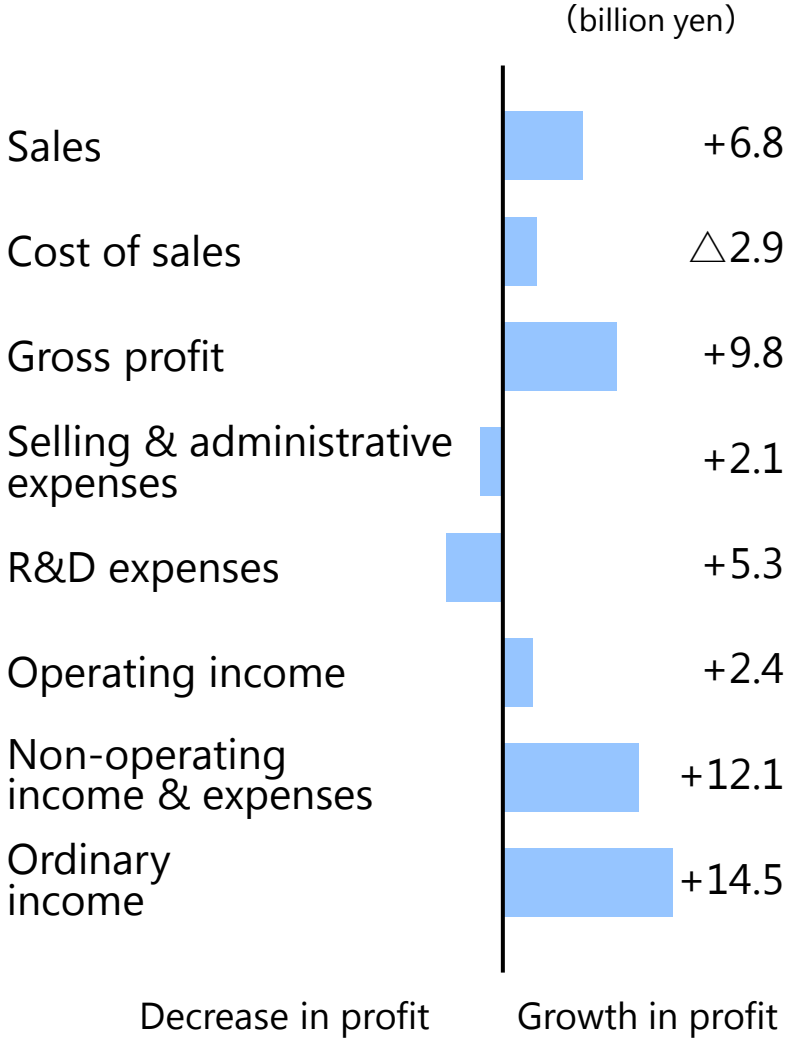
	FY2017			FY2016	YonY	
	Full year forecasts	Apr.-Dec. results	Progress vs. forecasts (%)	Apr.-Dec. results	change (%)	change
Sales	**345.0**	**263.4**	76.3	256.5	2.7	6.8
[Royalty* income]	**125.8**	**91.0**	72.3	74.4	22.4	16.6
Cost of sales	22.2 [34.9] **76.5**	21.5 [32.9] **56.7**	74.1	23.3 [32.7] 59.7	(4.9)	(2.9)
Gross profit	**268.5**	**206.6**	77.0	196.9	5.0	9.8
SG&A expenses	44.9 **155.0**	44.2 **116.5**	75.2	42.6 109.2	6.7	7.4
Selling & administrative expenses	29.0 **100.0**	26.9 **70.9**	70.9	26.8 68.8	3.0	2.1
R&D expenses	15.9 **55.0**	17.3 **45.6**	82.9	15.7 40.3	13.1	5.3
Operating income	32.9 **113.5**	34.2 **90.1**	79.4	34.2 87.7	2.7	2.4
Non-operating income & expenses	**P18.5**	**P15.3**	83.0	P3.3	-	12.1
Ordinary income	38.3 **132.0**	40.0 **105.5**	79.9	35.5 91.0	15.9	14.5

Note: The inside of [ ] is percentage of cost of sales to sales excluding royalty income

* Royalty income from ViiV (HIV franchise) and Astra Zeneca (Crestor®)

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

- **Y on Y comparison**



Main Variation Factors

- Sales
  - Sales expansion of strategic products
  - Increased royalty income for HIV franchise
  - Received payments* from Roche regarding baloxavir marboxil (S-033188)
    - 2Q: ca. 10.0 B yen
    - 3Q: ca. 8.0 B yen
- Cost of sales
  - Cost of sales ratio
    - Improved by 1.8%: Increase in royalty income
  - Cost of sales ratio excluding royalty income:
    - Increased by 0.2%: Effect of product mix (Increase in manufacturing of API for dolutegravir)
- SG&A expenses
  - Selling & administrative expenses: 2.1 billion yen
    - Advanced investment for new products
  - R&D expenses: +5.3 billion yen (Y on Y comparison +3.4 billion yen in 1H)
    - Investment for global development of baloxavir marboxil
- Non-operating income & expenses
  - Received dividend:
    Global sales growth of HIV franchise and dividend payment in accordance with the revised contract with ViiV
    - → Receive dividend from ViiV quarterly

Note: Underlined part is the major change point in 3Q
* Payments both for development progression events and for obtaining successful results

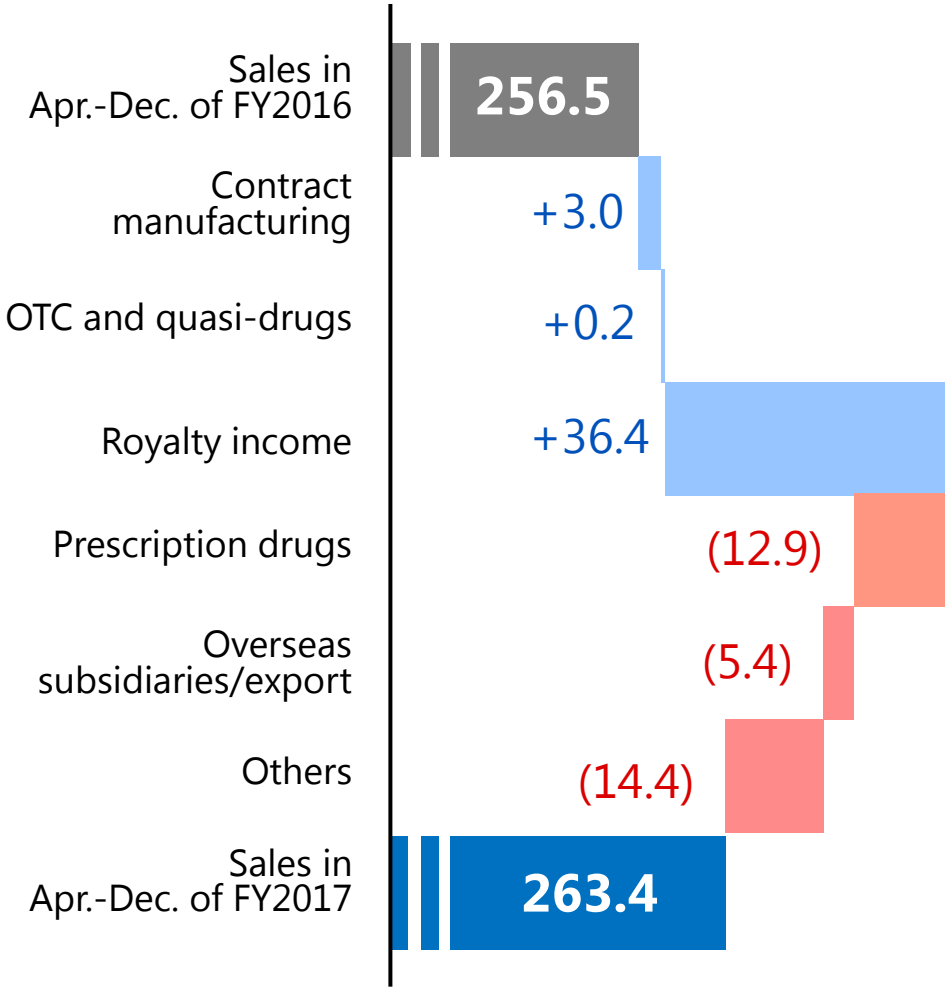
Sales by Segments (Consolidated)

(Unit B yen)

	FY2017			FY2016	YonY	
	Full year forecasts	Apr.-Dec. results	Progress vs. forecasts (%)	Apr.-Dec. results	change (%)	change
Prescription drugs	**144.1**	**108.4**	75.2	121.2	(10.6)	(12.9)
Overseas subsidiaries/export	**25.5**	**17.5**	68.4	22.9	(23.8)	(5.4)
Shionogi Inc.	**11.2**	**8.4**	74.7	13.8	(39.6)	(5.5)
Osphena®	**3.9**	**3.0**	76.3	3.3	(10.2)	(0.3)
Contract manufacturing	**15.4**	**11.8**	76.4	8.8	33.8	3.0
OTC and quasi-drugs	**7.0**	**5.7**	81.7	5.5	3.7	0.2
Royalty income	**150.3**	**118.1**	78.5	81.7	44.6	36.4
Royalty income for the sales of HIV franchise and Crestor®	**125.8**	**91.0**	72.3	74.4	22.4	16.6
HIV franchise	**103.3**	**74.0**	71.6	49.3	50.3	24.8
Crestor®	**22.5**	**17.0**	75.4	25.1	(32.4)	(8.1)
Others	**2.7**	**2.0**	74.1	16.4	(87.9)	(14.4)
Total	**345.0**	**263.4**	**76.3**	**256.5**	**2.7**	**6.8**

Y on Y comparison and Main Variation Factors (Sales by Segments)

- **Y on Y comparison** (billion yen)



Main Variation Factors
(YonY change: +6.8 billion yen, +2.7%)

- Contract manufacturing
  - Increase in API for dolutegravir
- Royalty income
  - Increased royalty income for HIV franchise
  - Decreased royalty income for Crestor®
  - Received payments* from Roche regarding baloxavir marboxil
    - 2Q: ca. 10.0 B yen
    - 3Q: ca. 8.0 B yen
- Prescription drugs
  - Sales expansion of strategic products
  - Decreased sales due to transfer of marketing rights of long-listed drugs, etc.
- Overseas subsidiaries/export
  - Decreased royalty income for authorized generic in US
- Others
  - Received upfront payments for transferring the marketing rights for long-listed drugs in prior FY

Note: Underlined part is the major change point in 3Q
* Payments both for development progression events and for obtaining successful results

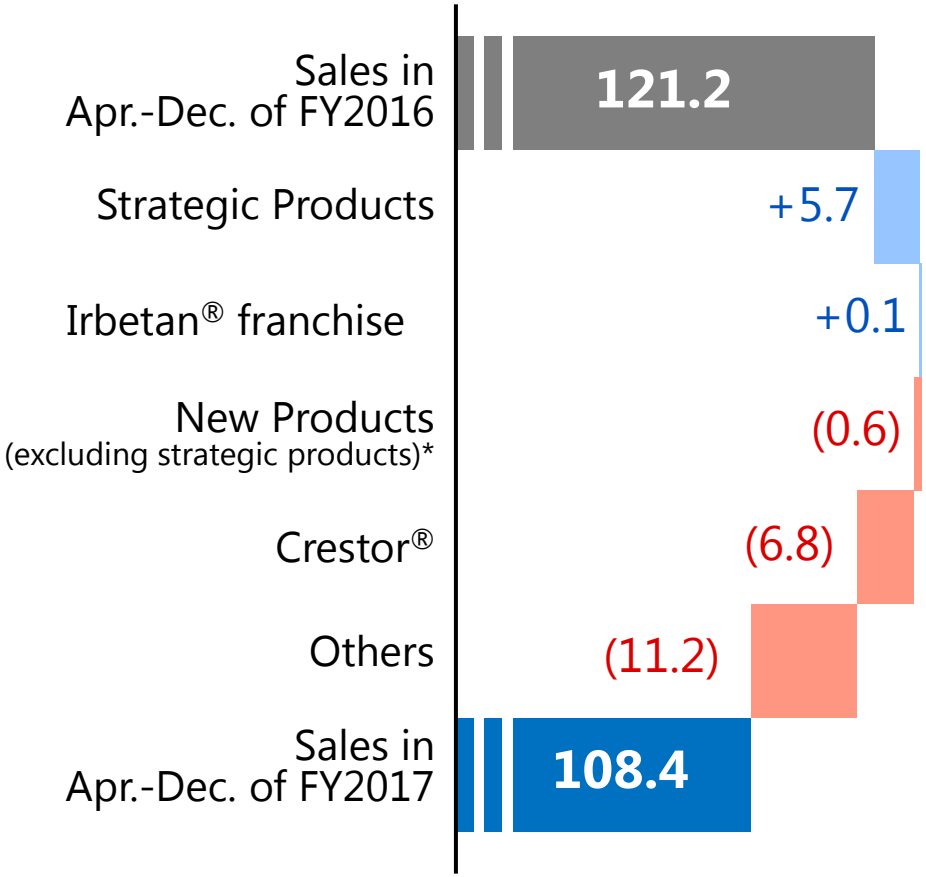
Sales of Prescription Drugs in Japan

(Unit B yen)

	FY2017			FY2016	YonY	
	Full year forecasts	Apr.-Dec. results	Progress vs. forecasts (%)	Apr.-Dec. results	change (%)	change
Cymbalta®	26.0	18.2	70.3	14.2	28.8	4.1
Intuniv®	2.0	1.2	60.2	-	-	1.2
Symproic®	0.60	0.38	62.8	-	-	0.38
Total of Strategic Products	28.6	19.8	69.4	14.2	40.1	5.7
Actair®	0.13	0.09	71.5	0.05	67.4	0.04
Mulpleta®	0.17	0.13	74.0	0.09	38.4	0.04
Pirespa®	6.0	4.9	82.6	4.5	8.5	0.4
OxyContin® franchise	8.9	7.0	78.9	7.7	(9.2)	(0.7)
Rapiacta®	2.8	1.2	44.2	1.2	(1.7)	(0.0)
Brightpoc® Flu	0.92	0.53	57.4	0.56	(4.8)	(0.03)
Glashvista®	0.31	0.20	62.6	0.52	(62.6)	(0.33)
Total of New Products	47.7	33.9	71.1	28.9	17.5	5.0
Crestor®	34.4	26.3	76.4	33.1	(20.5)	(6.8)
Irbetan® franchise	14.8	11.9	80.2	11.8	0.7	0.1
Others	47.2	36.3	76.9	47.5	(23.6)	(11.2)
Prescription drugs	**144.1**	**108.4**	**75.2**	**121.2**	**(10.6)**	**(12.9)**

Y on Y comparison and Main Variation Factors
(Sales of Prescription Drugs in Japan)

- **Y on Y comparison** (billion yen)



Main Variation Factors (YonY change: (12.9) billion yen, (10.6)%)

- Strategic Products
  - Sales** expansion of Cymbalta® in the pain area (+28.8% vs prior FY)
  - Maximizing the value of Intuniv®
- Crestor®
  - Decreased sales due to early uptake of generics for Crestor®
- Others
  - Decreased sales due to transfer of marketing rights of long-listed drugs, etc.

*New Products (excluding strategic products):
Actair®, Mulpleta®, Pirespa®, OxyContin® franchise, Rapiacta®, Brightpoc® Flu, and Glashvista®
** Sales of Cymbalta®: Remuneration for promotional activity from Eli Lilly Japan K.K.

Cited from presentation material of 1H FY2017 Financial Results

Key Actions in Response to Shionogi's Business Environmental Changes in 2H FY2017 -1

- **Sales in Japan**
  - Maintaining sales growth of new products
    - > Cymbalta®: Maximizing the value in the pain area
    - > Intuniv®: Providing more information about ADHD and Intuniv® to support further uptake
    - > Oxycodone family: Preparation for launch of tamper resistant formulation
  - Maximizing the value of our anti-flu drugs
    - > Baloxavir marboxil: Preparation for launch
    - > Rapiacta®: Collecting efficacy and safety data in repeat-dose study of patients with underlying respiratory disease
- **Overseas Business**
  - Osphena®: Maximizing the value of Osphena® in collaboration with Duchesnay Inc. and preparation for submission of the NDA for vaginal dryness to FDA
  - Symproic®: Collaboration with Purdue Pharma L.P. for a smooth launch
  - Developing our marketing strategy to maximize the value of cefiderocol and Mulpleta® in hospital/highly-specialized markets

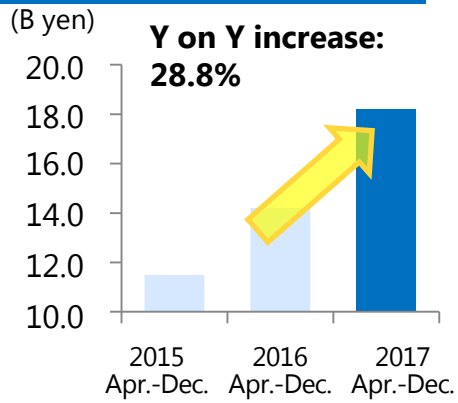
Strengthen and Enhance the Sales of New Products -1-

Sales* growth of Cymbalta® in the pain area

- Pain indication
  - Sales growth especially in OA and CLBP driven by positive perception
- Depression indication
  - Largest market share
  - Further sales growth

<Ongoing key actions>

- Focus sales force resources mainly on the pain area

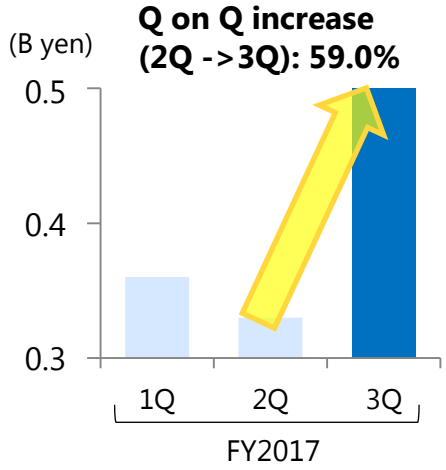


Maximizing the value of Intuniv®

- Increased prescription rate of Intuniv® based on high level of satisfaction with its efficacy and safety
- By 8 months after launch, reached a sales level exceeding that of any other ADHD drug
- Expanding the understanding of ADHD and its treatment amongst healthcare providers

<Ongoing key actions>

- Growing the NRx share
- Helping patients who are unsatisfied with other ADHD drugs
  - Switch from the current treatment
  - Adjunctive use of Intuniv®



OA: osteoarthritis, CLBP: chronic low back pain, ADHD: Attention deficit hyperactivity disorder
* Sales of Cymbalta®: Remuneration for promotional activity from Eli Lilly Japan K.K.

Strengthen and Enhance the Sales of New Products -2-

Launched Oxycontin® tamper resistant formulation (on Dec. 8, 2017)

- **Contribution to a more vigorous society by preventing misuse and abuse of opioids for medical use**
  - Possible to prevent misuse by crushing in addition to abuse
  - Prompt switch from the current formulation to support the proper use
    - > Considering to switch also from the other opioids in future



Current formulation
Can be easily crushed

- Preventing the abuse of opioids for medical use
- Support proper use for pain management



Tamper resistant formulation
Difficult to manipulate for misuse and abuse

Maximizing the value of anti-flu drugs

- Baloxavir marboxil: Accelerate the preparation for launch
- Rapiacta®: Initiated patient registration in repeat-dose study in patients with underlying respiratory disease

Sales Expansion of New Drugs and Negative Impact of Generic Entries on Main Products

(Unit: B yen)

New drugs	Full year forecast	Apr.-Dec. results	To achieve FY2017 business plan
Growth of new drugs including Cymbalta®	+8.6	+5.0	• Sales expansion of three strategic products • Launched Oxycontin® tamper resistant formulation (on Dec. 8, 2017)
Launch of generics for Crestor® and Irbetan®	(9.2)	(6.7)	• focus on new drugs
Long-listed drugs, etc.	**Full year forecast**	**Apr.-Dec. results**	**To achieve FY2017 business plan**
Decreased sales of long-listed drugs including Flomox® Decreased stockpiling of Rapiacta®	(8.4)	(6.2)	• On track
Transferring the marketing rights for long-listed 24 drugs	(4.9)	(4.9)	• Transferring the marketing rights for 21 long-listed drugs to Kyowa Pharmaceutical Industry Co., Ltd. on Dec. 1, 2016
Prescription drugs	**(13.9)**	**(12.9)**	

Continuous focus on new drugs

Progress in Overseas Business

- **Symproic®/Rizmoic®***
  - Launched in US (in Oct. 2017)
  - Improving market access coverage and highlighting clinical differentiation should drive sales expansion through a collaboration with Purdue Pharma L.P.
  - NDA Submission under review in EU (Accepted for review Mar. 2017)
- **Osphena®**
  - Collaboration with Duchesnay Inc. for sales expansion
  - Vaginal dryness study: Preparation for NDA submission in US
- **Mulpleta®** (Lusutrombopag)
  - NDA submission in US (in Dec. 2017)
  - NDA submission in EU (in Jan. 2018)
- **Cefiderocol**
  - Global phase III studies are ongoing
    (1) Carbapenem-resistant study (2) HAP/VAP study

* Symproic®: Brand name in US, Rizmoic®: Planned brand name in EU
HAP: Hospital Acquired Pneumonia VAP: Ventilator Associated Pneumonia

Baloxavir marboxil: Strong Collaboration with Roche

Decided to accelerate NDA submission in US based on positive results of Phase II study in Japan and OwH* study

Received the payment (ca. 8.0 B yen) from Roche by the agreement to accelerated NDA submission in US

→ **Roche will conduct all global studies initiated from now on**

Maximizing the value of baloxavir marboxil globally through a stronger collaboration with Roche

* OwH: Otherwise healthy

Precise Management of Total Costs

- **Total cost management scheme which combines selling & administrative expenses and R&D expenses into one unified expense budget**
  - Total cost management of SG&A expenses (Progress: 75.2%)
    - > Careful control of selling & administrative expenses (Progress: 70.9%)
    - > Increase in R&D expenses (Progress: 82.9%)
- **Advanced investment to accelerate R&D for growth drivers**
  - Baloxavir marboxil : Good progress in HR* study
  - Actions to maximize the value of baloxavir marboxil

Targeting revenue and profit growth in FY2017 based on precise total cost management while expanding investment in growth drivers

*HR: High risk

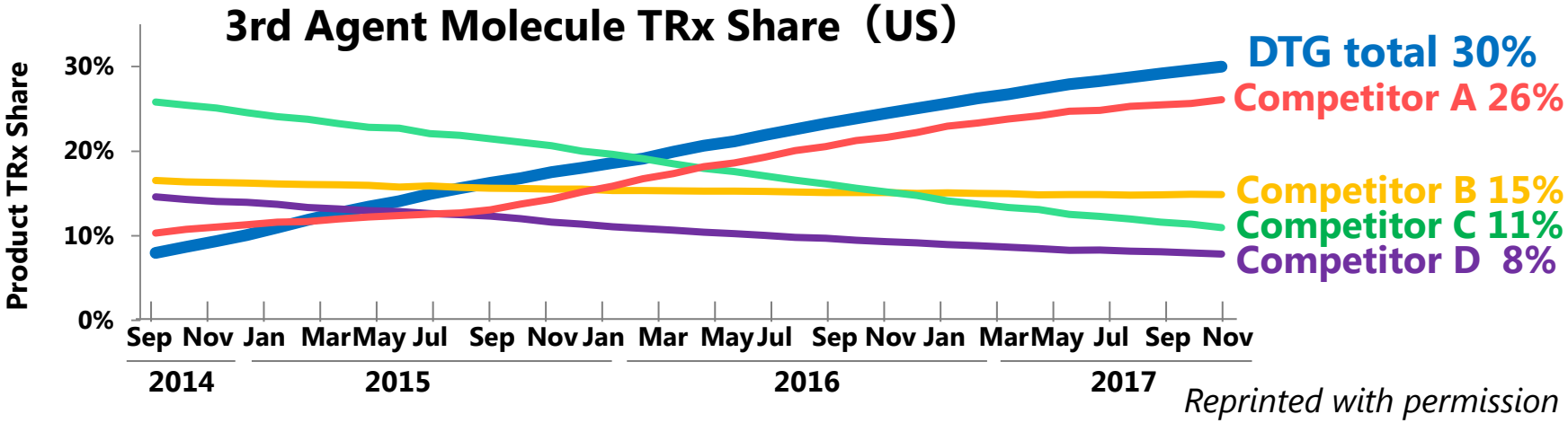
Progress in 3Q FY2017*

Strategic alliance	Phase I, II	Phase III	Submission Approval	Launch
Accenture ・Strategic digital transformation agreement **PeptiDream** ・Progress in Project 2 & 3 **PharmaIN** ・Initiated research collaboration	Global		**Mulpleta®** ・NDA submission (in US) **Mulpleta®** ・NDA submission (in EU)	**Symproic®** ・Steady increase of prescriptions
	In Japan	**Baloxavir marboxil** ・**Initiated pediatric study (granules)**	**Baloxavir marboxil** ・Passed through the Special Committee on Drugs	**Strategic products and new products** ・Sales growth **Oxycodone** Tamper resistant formulation ・Launched **Rapiacta®** ・Initiated clinical study
・Infectious diseases ・Pain/CNS ・Frontier	Out-licensed	**CAB+RPV (LAP)** ・Initiated every two months study **CAB (LAP)** ・Initiated prevention study (for female)	**Osphena®** ・Preparation for NDA submission	**Juluca®(DTG/RPV)** ・Launch (in US) **HIV franchise** ・Increase royalty income and dividend through global sales growth

* Change from Nov. 1, 2017 to Feb. 4 2018 is only described
DTG: dolutegravir RPV: rilpivirine CAB:cabotegravir LAP: long acting parenteral formulation

Growth and Progress of HIV Franchise

Prescription trend in US（TRx Share）



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Development status of the integrase inhibitor franchise

- **Juluca®**: DTG/RPV (Oral): Launched in US (in Dec. 2017)
- **DTG+3TC**: PhIII study is ongoing -> Planning to launch in FY2019
- **CAB+RPV** (LAP): Expect to improve adherence based on high convenience
  PhIII study is ongoing -> Planning to launch in FY2020
  Initiated PhIII study of every two months administration (in Nov. 2017)
- **CAB**(LAP) : Prevention study of every two or three months administration
  -> Planning to launch after FY2020

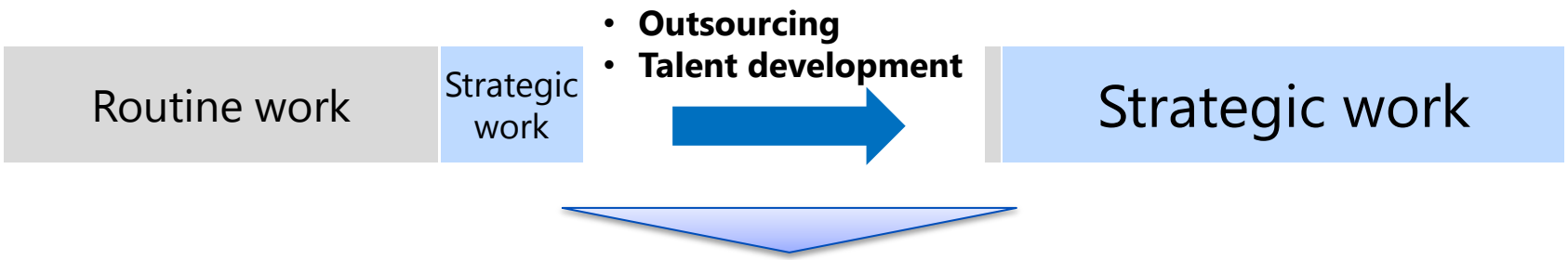
Strategic Alliances with Accenture (in Dec. 2017)

Strengthening the basis of IT organization

- Improving productivity in IT operation service
  - Save costs and resources in operation of IT systems by outsourcing routine work
  - Focus our resources on strategic work
  - Enhance capabilities of our IT division with Accenture's support

Talent development

- Improving IT literacy and business literacy
  - Investment in human resources through a knowledge-transfer program and utilizing costs and resources saved through outsourcing routine work



Promote innovation by improving IT literacy and business literacy

2. Shareholder Return

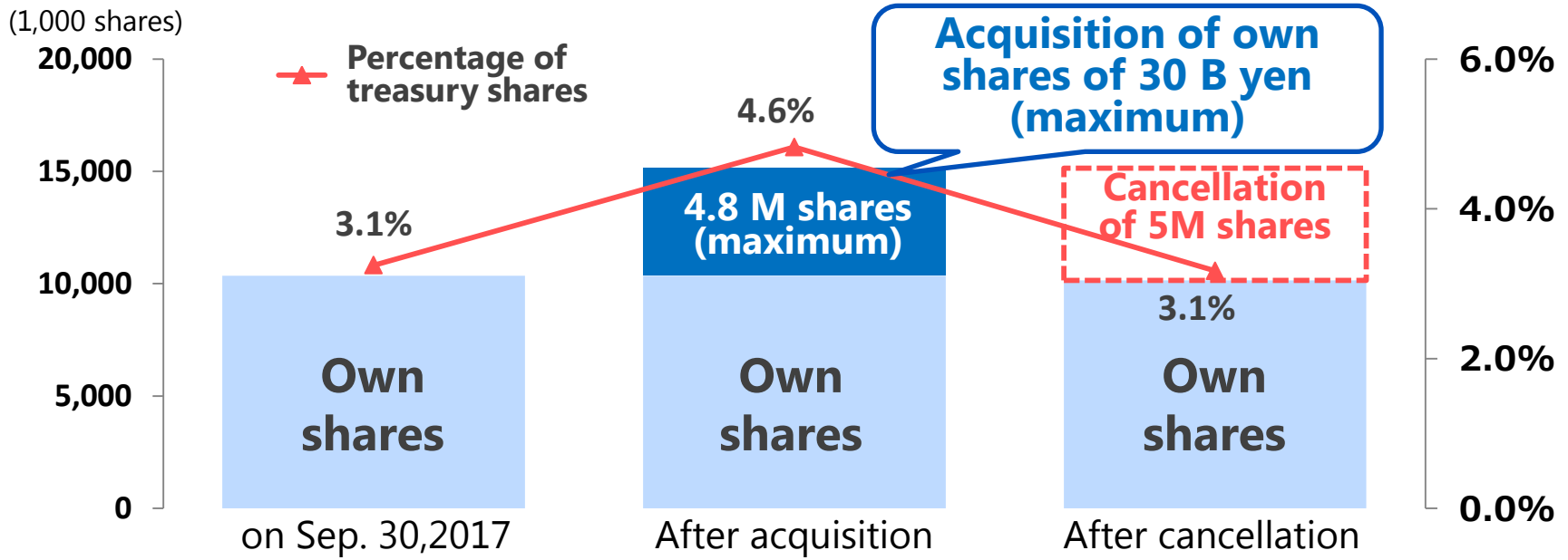
Acquisition of Own Shares and Cancellation of Treasury Shares

Acquisition of own shares

- Total number of shares to be acquired:
  4.8 M shares (maximum)
- Total amount of acquisition cost:
  30 B yen (maximum)
- Planned period of acquisition:
  From December 1, 2017 to February 28, 2018

cancellation of treasury shares

- Total number of shares to be cancelled:
  5.0 M shares
- Scheduled date of cancellation:
  March 12, 2018



Increase shareholder return and capital efficiency by following a flexible capital policy, aligning with strong business progress

Appendix

- Progress in Pipeline

- Target Milestones for Launch of New Products

Target Milestones for FY2017 (as of Jan. 2018)

Areas	Product	As of Apr. 1, 2017	Target for FY2017
Infectious disease	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Global:** **Preparation for NDA submission**	**US: NDA submission**
	baloxavir marboxil Influenza virus infection	**Global:** **Phase III** **Japan: Phase III** **(pediatric)**	**Japan: NDA submission**
Pain/CNS	**Intuniv®** ADHD (pediatric)	**Japan: Approved** ADHD (pediatric)	**Japan: Launch** ADHD (pediatric)
	Symproic® Opioid-induced constipation	**Japan: Approved**	**Japan: Launch**
	Symproic® Opioid-induced constipation	**US: Approved**	**US: Launch**
	Oxycodone Treatment of moderate to severe chronic pain	**Japan: NDA submission**	**Japan: Approval**
	Oxycodone Tamper resistant formulation	**Japan: NDA submission**	**Japan: Approval**
	Lisdexamfetamine ADHD (pediatric)	**Japan: Preparation for NDA submission** ADHD (pediatric)	**Japan: NDA submission** ADHD (pediatric)
	Cymbalta® Depression (pediatric)	-	**Japan: Phase III**
	S-600918 Neuropathic pain	**Japan: Phase I**	**Phase II** **(regions to be determined)**
Frontier	**Mulpleta®** Thrombocytopenia associated with chronic liver disease	**Global: Phase III**	**US and EU: NDA submission**
	Actair® (Pediatric allergic rhinitis caused by house-dust mite allergen	**Japan: NDA submission**	**Japan: Approval**

Red frame: Change since November 1 2017

ADHD: Attention deficit hyperactivity disorder

Pipeline (as of Jan. 2018)

SONG for you!

Preclinical	Phase I	Phase II	Phase III	Filed
Global		**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**S-033188 (baloxavir marboxil)** Influenza virus infection	**Naldemedine (EU)** Opioid-induced constipation
		S-120083 Inflammatory pain	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Mulpleta® (US)** Thrombocytopenia
Antibody drug candidate against pseudomonas	**S-117957** Insomnia	**S-707106** Type2 diabetes		**Mulpleta® (EU)** Thrombocytopenia
Central neuropathic pain	**S-237648** Obesity	**S-488210** Head and neck squamous cell carcinoma		
Obesity		**epertinib** Malignant tumor		
LCM inhalation		**S-588410** Bladder cancer		
In Japan		**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Baloxavir marboxil** Influenza virus infection
		S-237648 Obesity	**Intuniv®** ADHD (adult)	**Baloxavir marboxil** Influenza virus Infection (pediatric)
	S-010887 Neuropathic pain	**S-525606** Allergic rhinitis caused by Japanese cedar allergen	**Cymbalta®** Depression (pediatric)	**Oxycodone** Moderate to severe chronic pain
	S-600918 Neuropathic pain	**S-588410** Bladder cancer	**S-588410** Esophageal cancer	**Oxycodone** Tamper resistant formulation
	S-770108 Idiopathic pulmonary fibrosis		**Baloxavir marboxil** Influenza virus infection (oral, granule)	**Lisdexamfetamine** ADHD (pediatric)
				Actair® Pediatric patients with perennial allergic rhinitis
Out-licensed	**GSK3342830** Multidrug-resistant Gram-negative bacterial infections		**DTG+3TC** Treatment for HIV infection	• **Infectious diseases**
			CAB LAP Prevention for HIV infection	• **Pain/CNS**
Janssen/Shionogi Project compound Alzheimer's disease			**CAB + RPV LAP** Treatment for HIV infection	• **Metabolic disorder** • **Frontier**
			Janssen/Shionogi BACE inhibitor Alzheimer's disease	
			Osphena® Vaginal dryness associated with postmenopausal VVA	

Target Milestones for Launch of New Products

FY2017	FY2018	FY2019
Japanese business		
Symproic® **Intuniv®** ADHD (pediatric) **Oxycodone** Tamper resistant formulation Moderate to severe chronic pain **Actair®** Pediatric patients with perennial allergic rhinitis	**Baloxavir marboxil** **Lisdexamfetamine**	**Intuniv®** ADHD (adult)
Overseas business		
Symproic® (US)	**Cefiderocol** **Osphena®** Vaginal dryness associated with postmenopausal VVA **Mulpleta®** **Rizmoic®** (EU)	
Global out-licensed products		
	Juluca® (DTG/RPV)	**DTG + 3TC**

DTG: Dolutegravir , RPV: Rilpivirine, 3TC: Lamivudine

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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