

3rd Quarter of Fiscal 2016 Financial Results

Conference Call

February 2, 2017

SHIONOGI

Financial Results (Consolidated)

(Units: B yen)

	FY2016			FY2015	YonY
	full year forecasts	Apr.-Dec. results	progress vs. forecasts (%)	Apr.-Dec. results	change (%)
Sales	**334.0**	**256.5**	**76.8%**	225.9	**13.5%**
Operating income	**97.5**	**87.7**	**90.0%**	65.5	**34.0%**
Ordinary income	**105.5**	**91.0**	**86.2%**	66.5	**36.7%**
Profit attributable to owners of parent	**76.0**	**67.5**	**88.9%**	41.7	**62.1%**

- **Good business progress in 3Q**
- **Sales, Operating income and Profit attributable to owners of parent**
  - higher than the levels in Apr.-Dec. of any prior fiscal year for two consecutive years
- **Ordinary income**
  - higher than the levels in Apr.-Dec. of any prior fiscal year for eight consecutive years

Exchange rate (average)	FY2016 forecasts	FY2016 Apr.-Dec. results
USD ($) – JPY (¥)	**105**	**106.66**
GBP (£) – JPY (¥)	**140**	**141.90**
EUR (€) – JPY (¥)	**120**	**118.06**

Sales of Main Merchandise and Finished Goods (Consolidated)

(Units: B yen)

	full year forecasts	FY2016 Apr.-Dec. results	progress vs. forecasts (%)	FY2015 Apr.-Dec. results	YonY change (%)
Prescription drugs	**160.2**	**121.2**	**75.7**	**123.4**	**(1.8)**
Crestor®	42.9	33.1	77.1	33.6	(1.5)
Cymbalta®	19.3	14.2	73.4	11.5	23.1
Irbetan® franchise	15.8	11.8	74.8	12.0	(2.0)
Total of 3 key products	77.9	59.0	75.7	57.1	3.4
OxyContin® franchise	9.9	7.7	78.0	8.0	(3.7)
Finibax®	3.6	2.6	72.7	3.0	(12.2)
Pirespa®	6.0	4.5	75.6	4.6	(2.3)
Rapiacta®	2.3	1.2	53.9	0.4	178.5
Total of 7 strategic products	99.8	75.2	75.3	73.2	2.7
[percent of sales]	62.3%	62.0%		59.3%	
Overseas subsidiaries/export	**24.8**	**22.9**	**92.4**	**22.7**	**0.6**
Shionogi Inc.	13.6	13.8	101.6	13.2	4.6
Osphena®	4.8	3.3	69.0	3.8	(12.8)
Contract manufacturing	**12.4**	**8.8**	**70.9**	**5.4**	**65.1**
OTC and quasi-drugs	**7.0**	**5.5**	**78.5**	**3.8**	**44.6**
Royalty income	**112.3**	**81.7**	**72.7**	**68.4**	**19.5**
Royalty income from the sales of Crestor® and HIV franchise	**103.0**	**74.4**	**72.2**	**60.7**	**22.5**
Crestor®	32.8	25.1	76.6	35.7	(29.6)
HIV franchise	70.2	49.3	70.1	25.0	96.8
Others	**17.2**	**16.4**	**95.3**	**2.3**	**623.6**
Total	**334.0**	**256.5**	**76.8**	**225.9**	**13.5**

◆ Topics in the 3rd quarter

Prescription drugs in Japan

Growth of three key products and seven strategic products

- Crestor®: Launched OD tablets
  Increased prescriptions
- Cymbalta®: Increased 23.1%
  - Expanded sales in depression and depressive symptoms
  - Increased awareness in pain area

(Focused resources on maximizing the product value)

Overseas subsidiaries/export

Shionogi Inc.

- Increase in the prescriptions of Osphena® on track
- Increase in royalty income from the authorized generic (from 1Q to 3Q)

Royalty income

- HIV franchise: Continues to increase

Others

Upfront payments for transferring the marketing rights for long-listed drugs

Statement of Income (Consolidated)

(Units: B yen)

	full year forecasts	FY2016 Apr.-Dec. results	progress vs. forecasts (%)	FY2015 Apr.-Dec. results	YonY change (%)
Sales	**334.0**	**256.5**	**76.8**	225.9	13.5
[Royalty* income]	**103.0**	**74.4**	**72.2**	60.7	22.5
Cost of sales	23.4 [33.8] **78.0**	23.3 [32.7] **59.7**	**76.5**	24.4 [33.4] 55.2	8.1
SG&A expenses	47.5 **158.5**	42.6 **109.2**	**68.9**	46.6 105.3	3.7
Selling & general expenses	29.3 **98.0**	26.8 **68.8**	**70.2**	31.0 70.0	(1.6)
R&D expenses	18.1 **60.5**	15.7 **40.3**	**66.6**	15.6 35.3	14.2
Operating income	29.2 **97.5**	34.2 **87.7**	**90.0**	29.0 65.5	34.0
[Excluding royalty* income]	**(5.5)**	**13.4**	**-**	4.8	-
Non-operating income and expenses	**P8.0**	**P3.3**	**-**	P1.1	-
Ordinary income	31.6 **105.5**	35.5 **91.0**	**86.2**	29.5 66.5	36.7

◆ Topics in the 3rd quarter

Cost of sales

Cost of sales ratio: Improved
- Increase in sales of Cymbalta®
- Cost reduction
- Increase in royalty income
- Upfront payments for transferring the marketing rights for long-listed drugs

SG&A expenses

Total cost management
- Strategic investment by focusing on efficiency and prioritization and total cost management
- Development costs for S-033188 will increase in 4Q

Non-operating income and expenses

Dividends
- Received interim dividend from ViiV

Foreign exchange profit or loss
- Loss: 0.3 B yen from Apr. to Dec.

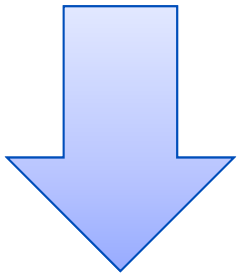
Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties
* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

Key Actions in 2H FY2016
(cited from Financial Results in 1H FY2016)

Key Points of FY2016 Financial Forecasts

Increased from original forecasts

- **Royalty income from HIV franchise**
- **Investments for growth drivers: S-033188 and cefiderocol**



- **Strengthen and enhance Japanese/overseas business**
- **Total cost management**

Exceed original FY2016 profit targets while expanding investment in growth drivers

Progress in the Pipeline and Planned Investments in the 4th Quarter

Progress in 2H FY2016

Strengthen and enhance new products*

- Cymbalta®
  - NDA approval for pain associated with osteoarthritis
- OxyContin®
  - NDA submission for TR formulation and chronic pain
- Naldemedine (Overseas)
  - Established alliance with Purdue Pharma

Global development

- S-033188
  - Phase III (OwH、HR): First Patient In
  - Phase III (pediatric) in Japan: First Patient In
- Cefiderocol
  - Initiated Phase III (HAP/VAP)
  - Top-line results of cUTI study of cefiderocol

Investments in growth drivers in 4Q FY2016

Strengthen and enhance new products*

- Cymbalta®
  - Maximize the value of Cymbalta® by strengthening marketing activities in pain area
- OxyContin® franchise + naldemedine
  - OxyContin®: Prepare for the launch of TR formulation
  - Naldemedine (Japan): Discuss in Drug Committee Meeting, receive NDA approval, establish platform for the launch
- Guanfacine hydrochloride
  - Receive NDA approval, establish platform for the launch

Global development

- Naldemedine (Overseas)
  - Plan to receive NDA approval in the US in Mar. 2017 (PDUFA date: Mar. 23, 2017)
  - Plan to submit NDA in Europe in Mar. 2017

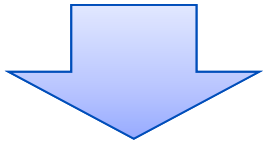
* Definition of new products is referred to Appendix (cited from Updates to SGS2020)

TR: Tamper resistant
cUTI: Complicated urinary tract infection
OwH: Otherwise healthy
HR: High risk
HAP: Hospital Acquired Pneumonia
VAP: Ventilator Associated Pneumonia

Growing by New Products in FY2017

Changes in Shionogi's business environment

- Strong revenue base from HIV franchise, and stable royalty income from Crestor®
- Transfer of the marketing rights for long-listed drugs, and possibility of the launch of generic version of Crestor® and Irbetan® in Japan



Sustained Growth by New Products in FY2017

Top-line growth by new products

Japan	Overseas
• Cymbalta® • OxyContin® franchise • Naldemedine • Guanfacine hydrochloride	• Naldemedine - Maximize the value of product through the collaborative launch with Purdue Pharma L.P. • Osphena® - Maximize the value of product

Actions for Shionogi's Sustained Growth and to Increase Corporate Value in the Mid-to-Long term

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Top-line Results of cUTI Study of Cefiderocol

- **Met the FDA pre-specified primary endpoint in efficacy for non-inferiority vs IPM/CS (Fig. 1)**

  ⇒ Superiority to IPM/CS at TOC

- **Well-tolerated**

⇒ Plan to submit NDA in the US in 1H FY2017

Fig. 1: Results of primary efficacy endpoints

Microbiological ITT Population	S-649266 (N=252)	IPM/CS (N=119)	Treatment Comparison*	
			Difference	95%CL
Composite of Clinical and Microbiological Outcome at TOC	183 (72.6%)	65 (54.6%)	18.58%	(8.23, 28.92)

Percentage is calculated using the number of subjects in the column heading as the denominator.

* Treatment difference (S-649266 minus IPM/CS) is the adjusted estimate of the difference in the responder rate between the 2 treatment arms. The adjusted difference estimates and the 95% Cis (2-side) are calculated using a stratified analysis with Cochran-Mantel Haenszel weights based om the stratified factor at baseline (cUTI with or without pyelonephritis vs. acute uncomplicated pyelonephritis).

cUTI: Complicated urinary tract infection
IPM/CS: imipenem/cilastatin
CI: confidence interval
TOC: test of cure



Provide New Treatment Options in Pain Management

SONG for you!

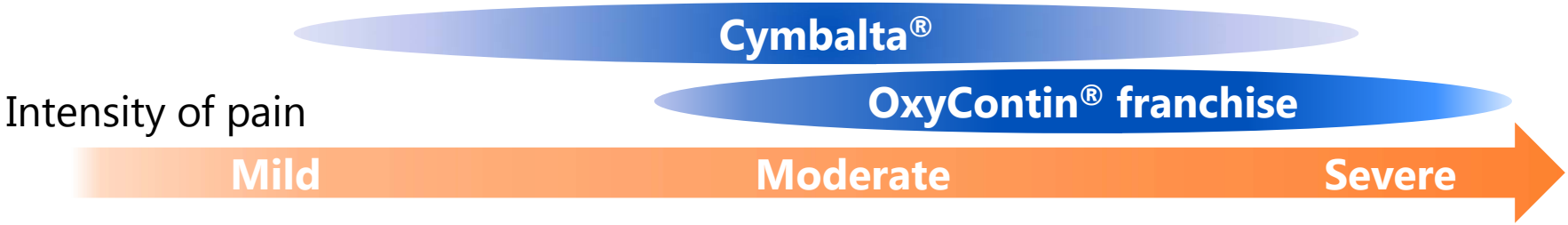
Cymbalta®

Additional indications for Pain

- Pain associated with diabetic neuropathy
- Pain associated with fibromyalgia
- Pain associated with chronic low back pain
- Pain associated with osteoarthritis

OxyContin® franchise and Naldemedine

- Analgesic effect for chronic pain ⇒ **NDA submission for additional indications**
- Proper medical use of opioids ⇒ **NDA submission for tamper resistant formulation**
- Opioid-induced constipation ⇒ **Development of naldemedine**



OIC: opioid-induced constipation



Maximize the Value of Naldemedine

Joint U.S. commercialization with Purdue Pharma L.P. to maximize the value of naldemedine

Purdue Pharma L.P.

- Part of a global network of independent associated companies that includes the Mundipharma group of companies
- Known for pioneering research in chronic pain and opioids with abuse-deterrent properties
- Leader in the pain treatment market
- Large and experienced sales force
- Long-standing collaboration with Shionogi in pain R&D

Achieve a strong launch of naldemedine while controlling our costs and utilize the product *as a part of care for patients treated with opioids*



Supporting Our Children's Future

SONG for you!

Aiming to create vigorous society:
Providing patients with developmental disabilities and/or central nervous system diseases with life-improving support

Partnership with the Osaka Prefectural Government

- Supporting children for a healthy future
  - Healthcare support for children
  - Science programs
  - Support for children with developmental disabilities

Osaka Prefectural Government

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Established *the Office for Children's Bright Future* and supported its activities

Establishment of Japanese Group Companies

Internal environment

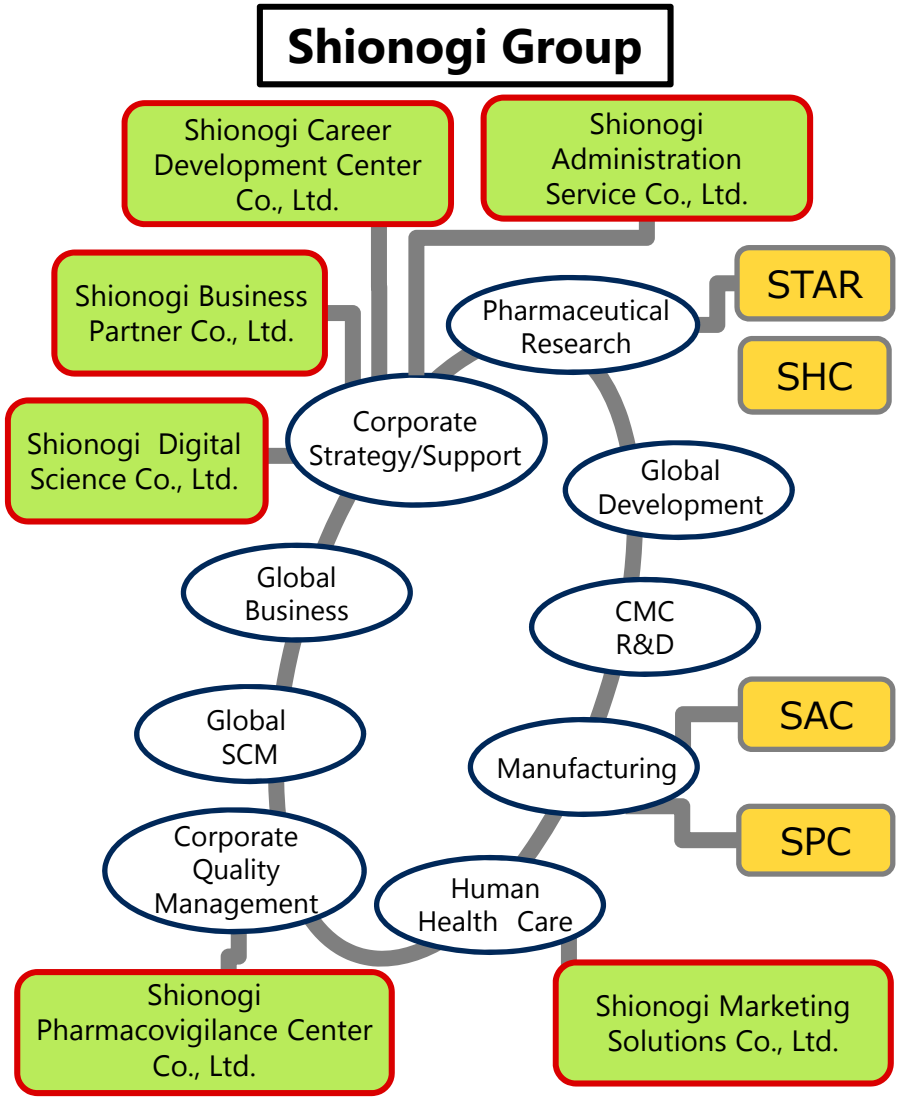
Low Productivity

- Without royalty, operating profit per employee is on a plateau

External environment

- **Measures to address the aging population**
- **Financial pressure on healthcare**

- **Improvement of Business Operations**
- **Response to requests from society**
  - Extension of employment period
  - Equal pay for equal work, etc.



Red frame: New Japanese group companies to be established in Apr. 2017

STAR: Shionogi Techno Advance Research Co., Ltd.
SAC: Shionogi Analysis Center Co., Ltd.
SPC: Shionogi Pharma Chemicals Co., Ltd
SHC: Shionogi Healthcare Co., Ltd.

Vision for SGS2020

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare



Appendix
- Progress in Our Pipeline -
- Transition of Royalty Income -

Target Milestones for FY2016

Areas	Product	As of Apr. 1, 2016	Target for FY2016	
Infectious disease	**Cefiderocol (S-649266)** Multidrug-resistant Gram-negative bacterial infections	Global: Phase II, III	US: NDA submission in preparation	US: Phase III (HAP/VAP) initiated
	S-033188 Influenza virus infection	Japan: Phase II / US: Phase I	Japan: Phase II completed	US: Phase I completed
			Global: Phase III initiated, Japan: Phase III (pediatric) initiated	
Pain/CNS	**Guanfacine hydrochloride** ADHD (pediatric)	Japan: NDA submission	Japan: Approval	
	Cymbalta® Pain associated with osteoarthritis	Japan: NDA submission	Japan: Approval	
	Naldemedine Opioid-induced constipation	Japan/US: NDA submission	Japan/US: Approval	EU: NDA submission
	Oxycodone Treatment of moderate to severe chronic pain	Japan: Phase III	Japan: NDA submission	
	Oxycodone Tamper resistant formulation	Japan: Phase I completed	Japan: NDA submission	
	Lisdexamfetamine ADHD (pediatric)	Japan: Phase III	Japan: Phase III completed	
Metabolic disorder	**S-237648** Obesity	Japan: Phase II	Japan: Phase II completed	US: Phase I initiated
Frontier	**Lusutrombopag** Thrombocytopenia associated with chronic liver disease	Global: Phase III	Global: Phase III	
	S-222611 Malignant tumor	EU: Phase I/II	EU: Phase I/II completed	

Red frame: Change since Nov. 1 2016
ADHD: Attention deficit hyperactivity disorder
HAP: Hospital Acquired Pneumonia
VAP: Ventilator Associated Pneumonia

Pipeline (as of Feb. 2017)

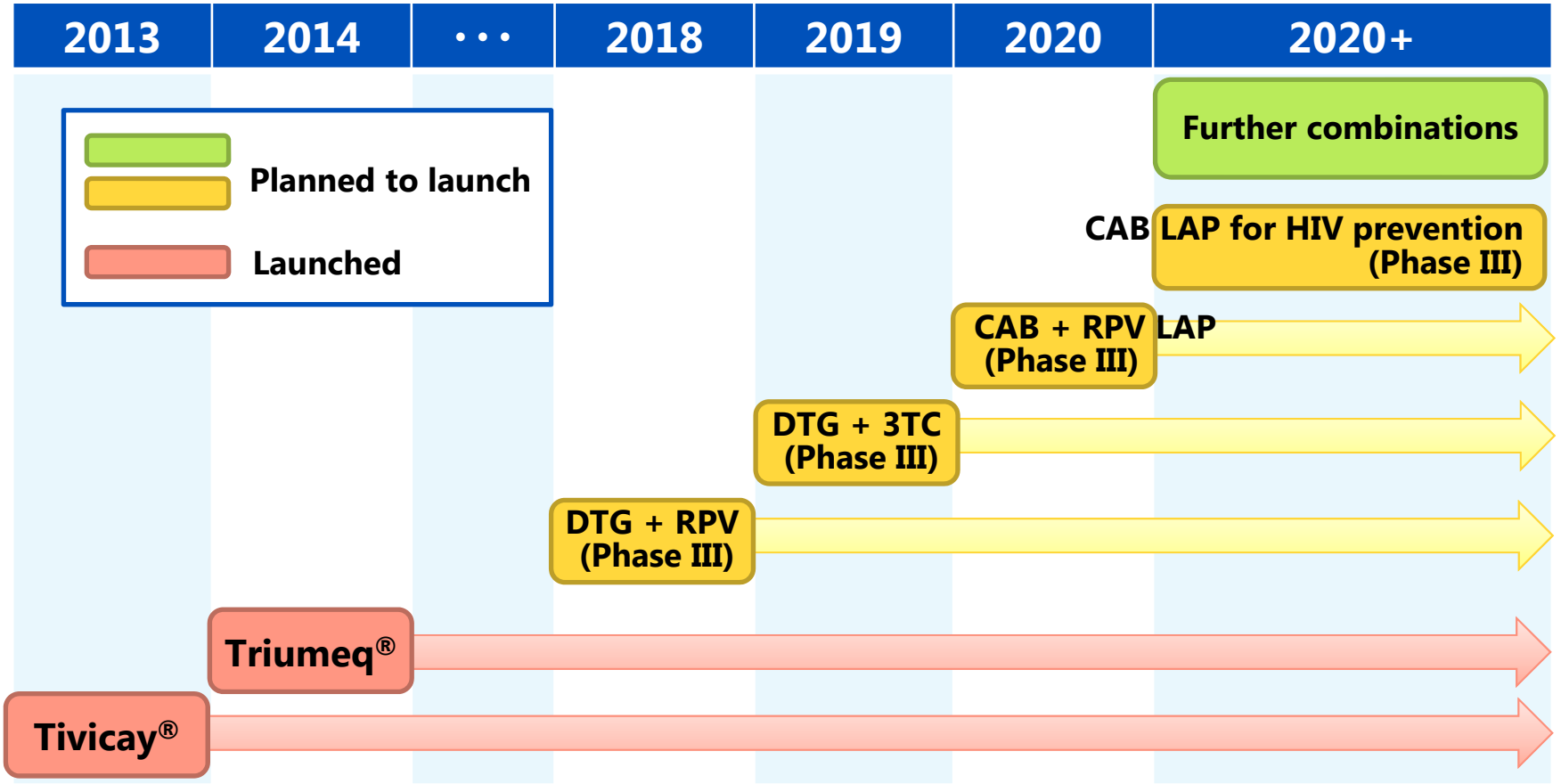
Non-clinical	Phase I	Phase II	Phase III	NDA submission
Antibody drug candidate against Pseudomonas	**【Global】**	**Cefiderocol (S-649266)** Multidrug-resistant Gram-negative bacterial infections	**S-033188** Influenza virus infection	
NTE inhalation	**S-120083** Inflammatory pain	**S-707106** Type2 diabetes	**Cefiderocol (S-649266)** Multidrug-resistant Gram-negative bacterial infections	
	S-117957 Insomnia	**S-488210** Head and neck squamous cell carcinoma	**Lusutrombopag** Thrombocytopenia	
	S-237648 Obesity	**S-222611** Malignant tumor	**Osphena®** Vaginal dryness associated with postmenopausal VVA	**Naldemedine** Opioid-induced constipation
		S-588410 Bladder cancer		
	【Japan】			
	Oxycodone Tamper resistant formulation	**Cefiderocol (S-649266)** Multidrug-resistant Gram-negative bacterial infections	**S-033188** Influenza virus infection	**Naldemedine** Opioid-induced constipation
	S-120083 Inflammatory pain	**S-237648** Obesity	**S-033188** Influenza virus Infection (pediatric)	**Guanfacine hydrochloride** ADHD (pediatric)
	S-010887 Neuropathic pain	**S-525606** Allergic rhinitis caused by Japanese cedar allergen	**Cefiderocol (S-649266)** Multidrug-resistant Gram-negative bacterial infections	**Oxycodone** Moderate to severe chronic pain
	S-600918 Neuropathic pain	**S-588410** Bladder cancer	**Lisdexamfetamine** ADHD (pediatric)	
			Guanfacine hydrochloride ADHD (adult)	**Infectious diseases**
			Actair® Pediatric patients with perennial allergic rhinitis	**Pain/CNS**
			S-588410 Esophageal cancer	**Metabolic disorder**
				Frontier

Pipeline (as of Feb. 2017)

Non-clinical	Phase I	Phase II	Phase III	NDA submission
【Out-licensed】			**Dolutegravir + rilpivirine** Treatment for HIV infection	
GSK3342830 Multidrug-resistant Gram-negative bacterial infections			**Dolutegravir + lamivudine** Treatment for HIV infection	**Infectious diseases** **Pain/CNS**
Janssen/Shionogi Project compound Alzheimer's disease			**Cabotegravir LAP** Prevention for HIV infection	
			Cabotegravir + rilpivirine LAP Treatment for HIV infection	
			Janssen/Shionogi BACE inhibitor Alzheimer's disease	

Red frame: Change since Nov. 2016
LAP: Long acting parenteral formulation

HIV Integrase Inhibitor Franchise
(cited from Financial Results in 1H FY2016)

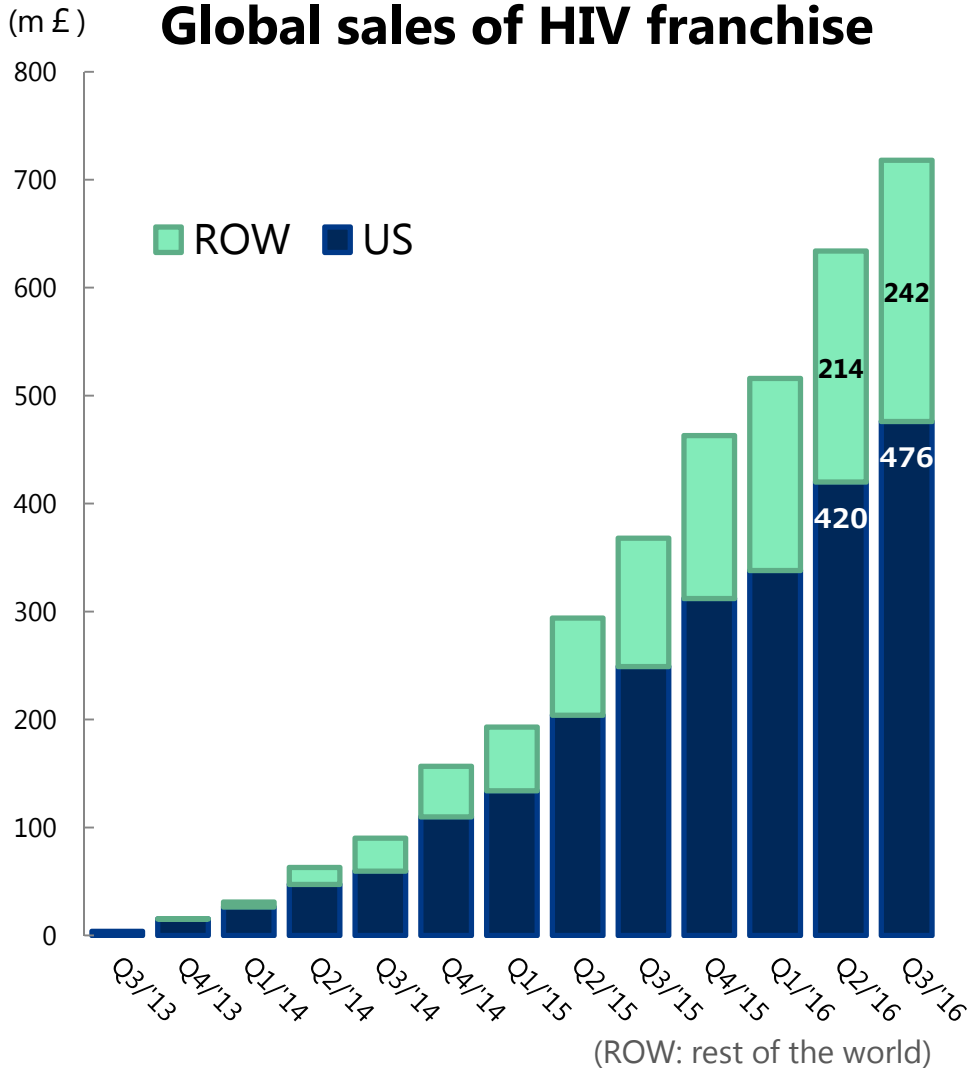


ViiV's strategy to develop new treatment regimens to address the needs of people living with HIV places our HIV integrase inhibitors at the core of therapy

LAP: Long acting parenteral formulation

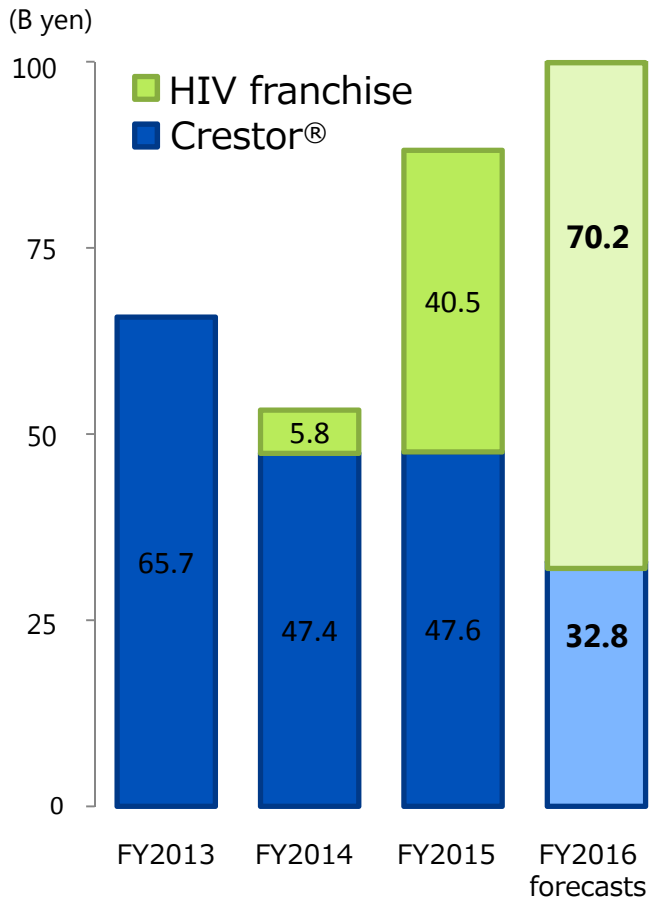
Global sales of HIV franchise and Royalty income (cited from Financial Results in 1H FY2016)

Global sales of HIV franchise



(ROW: rest of the world)

Royalty income from ViiV and AZ



Appendix
- Actions to Achieve FY2016 Business Plan-
- Definition of New Products -

Actions to Achieve FY2016 Business Plan
(cited from Financial Results in 1H FY2016)

Strengthen and enhance Japanese business

- **Cymbalta®**
  - Plan to expand indications: Pain associated with osteoarthritis
- **ADHD**
  - Plan to receive NDA approval for guanfacine hydrochloride
  - Establish platform for the launch

Strengthen and enhance overseas business

- **Naldemedine**
  - Continue to explore partnering options
  - Establish platform for the launch
- **Osphena®**
  - Expand market share
  - Continue Phase III clinical study for vaginal dryness

Global development

- **S-033188**
  - Initiate global Phase III trials
- **Cefiderocol**
  - Strong commitment to AMR issue

Cost management

- Focus resources on high priority business activities
- Implement the new cost management scheme which combines general expenses and R&D expenses into one unified expense budget

AMR: Antimicrobial resistance

Definition of New Products
(cited from Updates to SGS2020)

Pain/ CNS

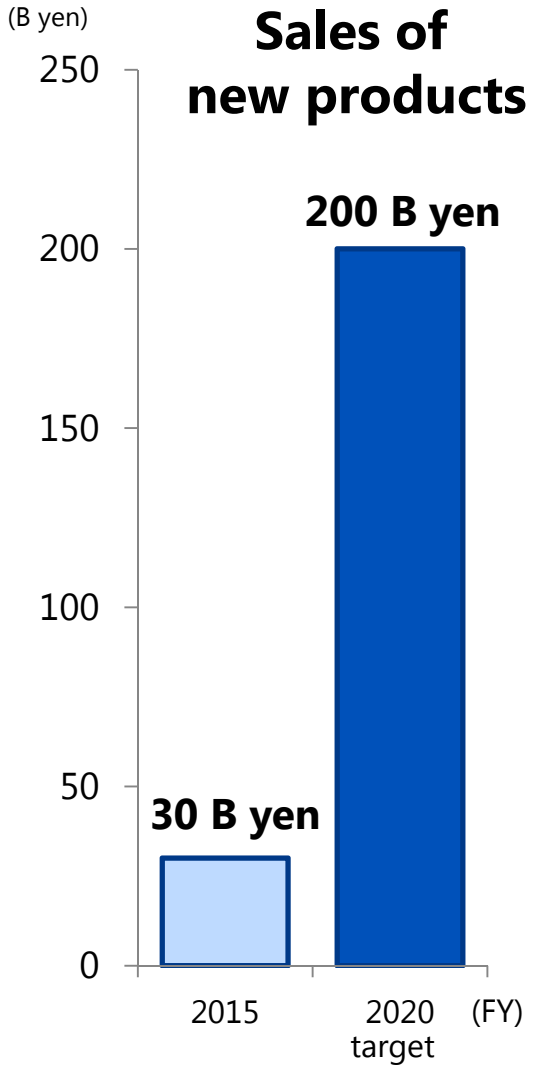
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine
- Guanfacine hydrochloride, lisdexamfetamine

Infectious diseases

- S-033188
- Cefiderocol (S-649266)
- Rapiacta®, flu diagnosis kit

Others

- Pirespa®
- Mulpleta® (S-888711)
- Actair®
- Glashvista®
- Osphena® (Senshio®)



Forward-Looking Statements

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