



**3rd Quarter of Fiscal 2016
Financial Results**
Conference Call

February 2, 2017



Financial Results (Consolidated)



(Units: B yen)

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

Key Actions in 2H FY2016

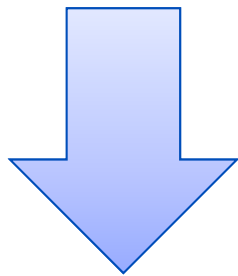
(cited from Financial Results in 1H FY2016)



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

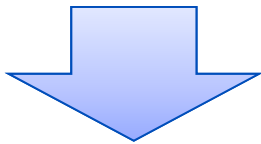


Growing by New Products in FY2017



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



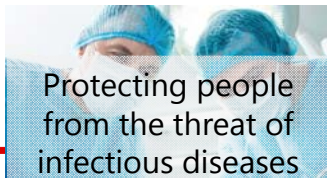
Sustained Growth by New Products in FY2017

Top-line growth by new products

Japan	Overseas
<ul style="list-style-type: none">• Cymbalta®• OxyContin® franchise• Naldemedine• Guanfacine hydrochloride	<ul style="list-style-type: none">• Naldemedine<ul style="list-style-type: none">- Maximize the value of product through the collaborative launch with Purdue Pharma L.P.• Osphena®<ul style="list-style-type: none">- Maximize the value of product



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



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 on the stratified factor at baseline (cUTI with or without pyelonephritis vs. acute uncomplicated pyelonephritis).



Provide New Treatment Options in Pain Management



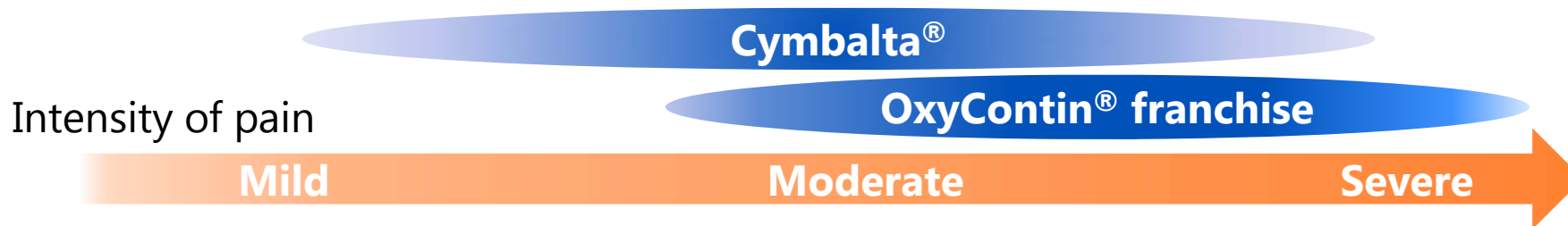
Cymbalta®

Additional indications for Pain

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





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



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

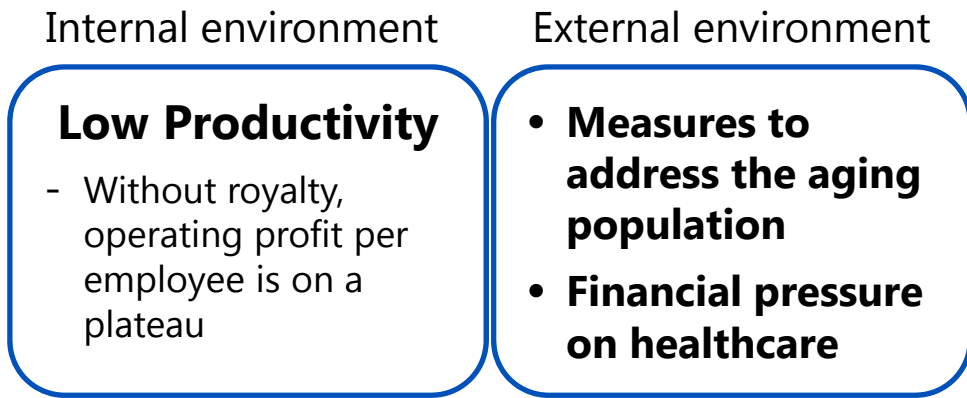
Partnership with the Osaka Prefectural Government

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

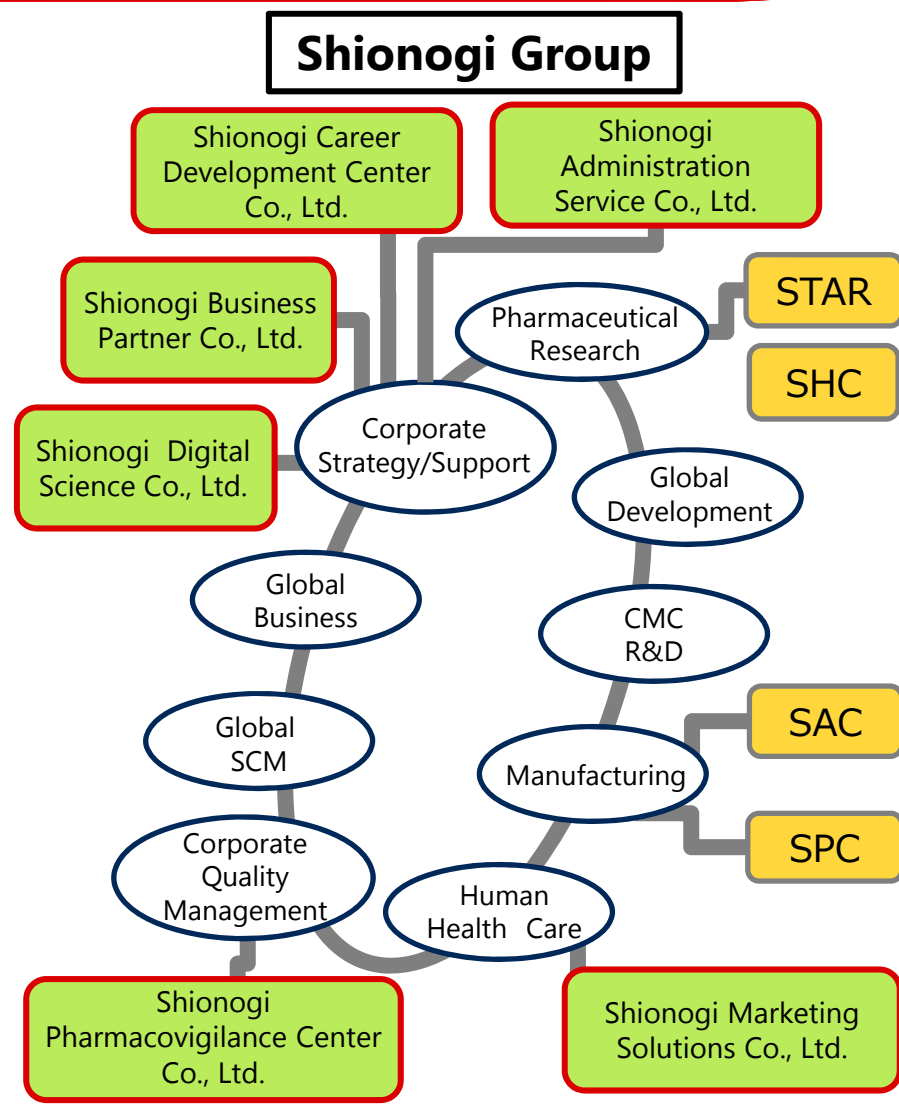


Established the Office for Children's Bright Future and supported its activities

Establishment of Japanese Group Companies



- **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

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

Pipeline (as of Feb. 2017)



Non-clinical	Phase I	Phase II	Phase III	NDA submission
<p>Antibody drug candidate against Pseudomonas</p> <p>NTE inhalation</p>	<p>【Global】</p> <p>S-120083 Inflammatory pain</p> <p>S-117957 Insomnia</p> <p>S-237648 Obesity</p>	<p>Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections</p> <p>S-707106 Type2 diabetes</p> <p>S-488210 Head and neck squamous cell carcinoma</p> <p>S-222611 Malignant tumor</p> <p>S-588410 Bladder cancer</p>	<p>S-033188 Influenza virus infection</p> <p>Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections</p> <p>Lusutrombopag Thrombocytopenia</p> <p>Osphena® Vaginal dryness associated with postmenopausal VVA</p>	<p>Naldemedine Opioid-induced constipation</p>
	<p>【Japan】</p> <p>S-120083 Inflammatory pain</p> <p>S-010887 Neuropathic pain</p> <p>S-600918 Neuropathic pain</p>	<p>Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections</p> <p>S-237648 Obesity</p> <p>S-525606 Allergic rhinitis caused by Japanese cedar allergen</p> <p>S-588410 Bladder cancer</p>	<p>S-033188 Influenza virus infection</p> <p>S-033188 Influenza virus Infection (pediatric)</p> <p>Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections</p> <p>Lisdexamfetamine ADHD (pediatric)</p> <p>Guanfacine hydrochloride ADHD (adult)</p> <p>Actair® Pediatric patients with perennial allergic rhinitis</p> <p>S-588410 Esophageal cancer</p>	<p>Naldemedine Opioid-induced constipation</p> <p>Guanfacine hydrochloride ADHD (pediatric)</p> <p>Oxycodone Moderate to severe chronic pain</p> <p>Oxycodone Tamper resistant formulation</p> <div style="border: 1px solid blue; padding: 5px;"> <p>Infectious diseases</p> <p>Pain/CNS</p> <p>Metabolic disorder</p> <p>Frontier</p> </div>

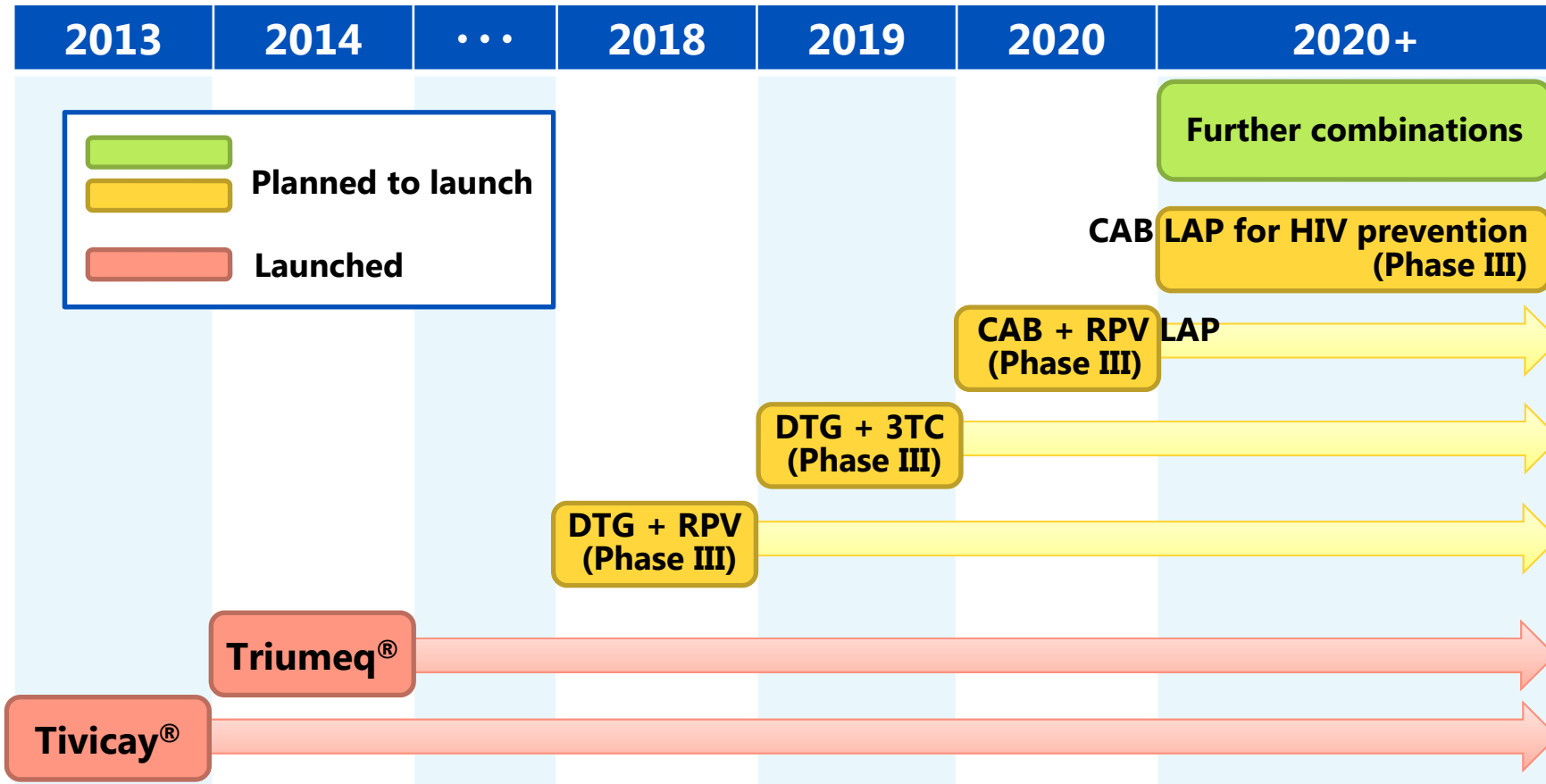
Pipeline (as of Feb. 2017)



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

HIV Integrase Inhibitor Franchise

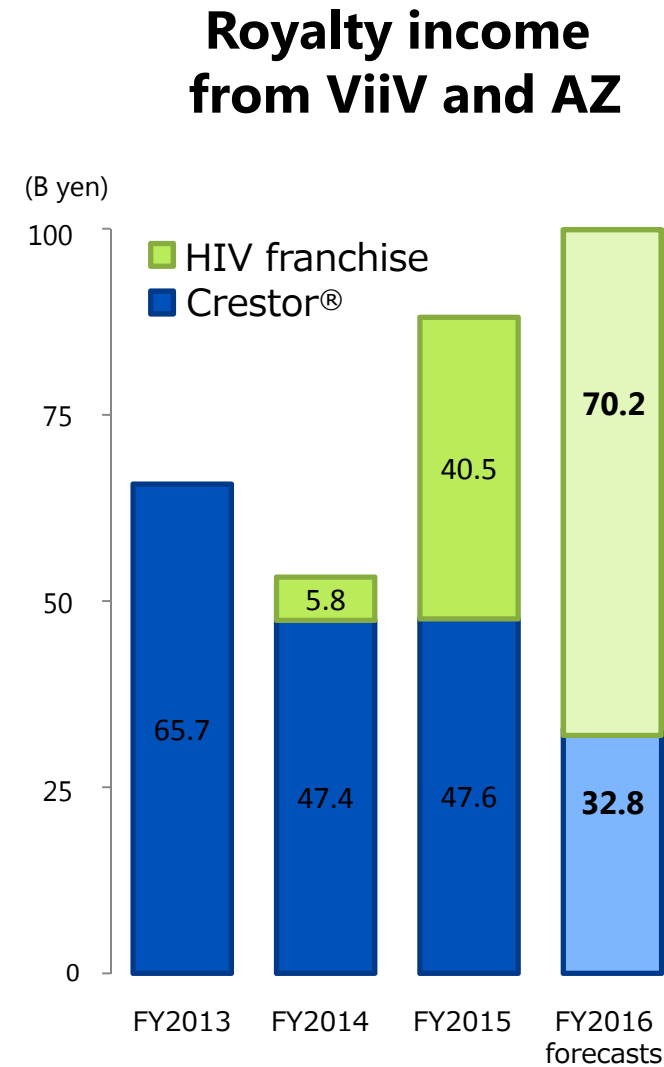
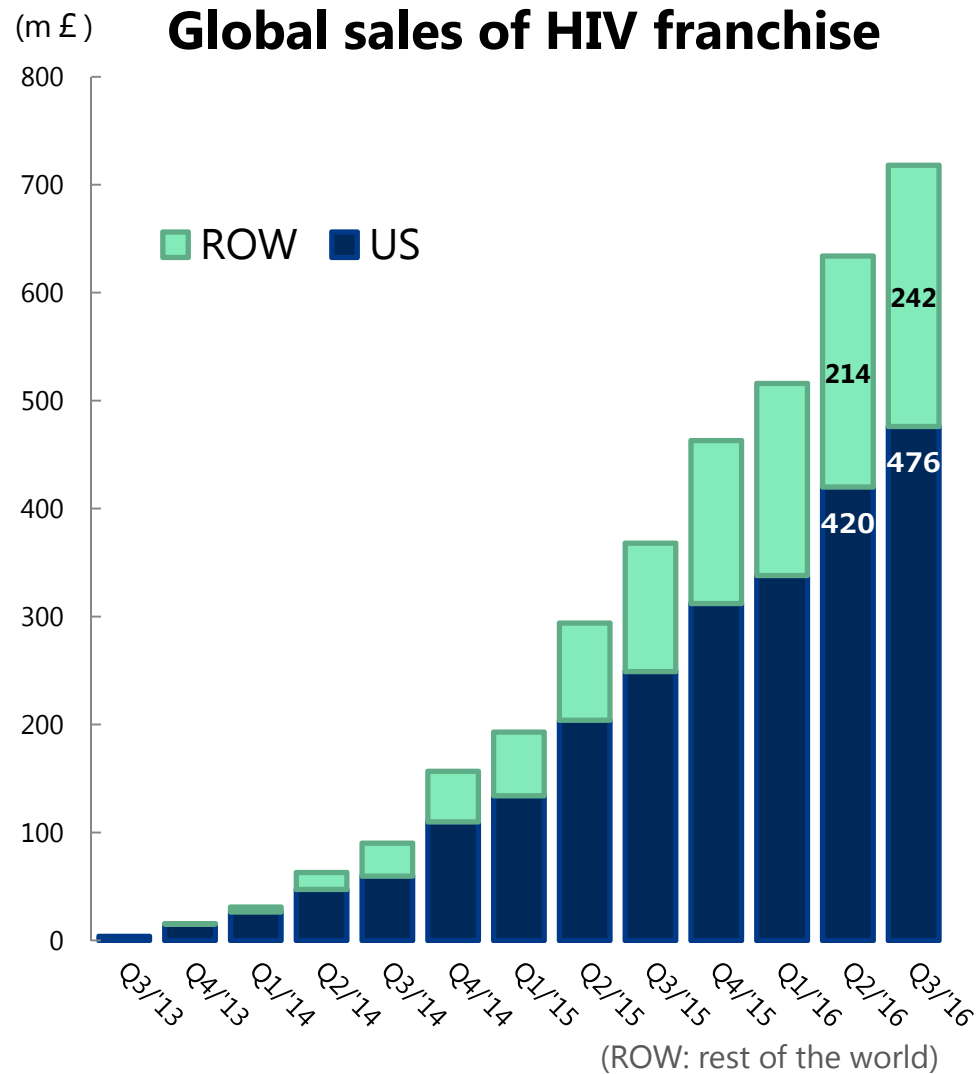
(cited from Financial Results in 1H FY2016)



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

Global sales of HIV franchise and Royalty income

(cited from Financial Results in 1H FY2016)





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

Definition of New Products

(cited from Updates to SGS2020)



**Pain/
CNS**

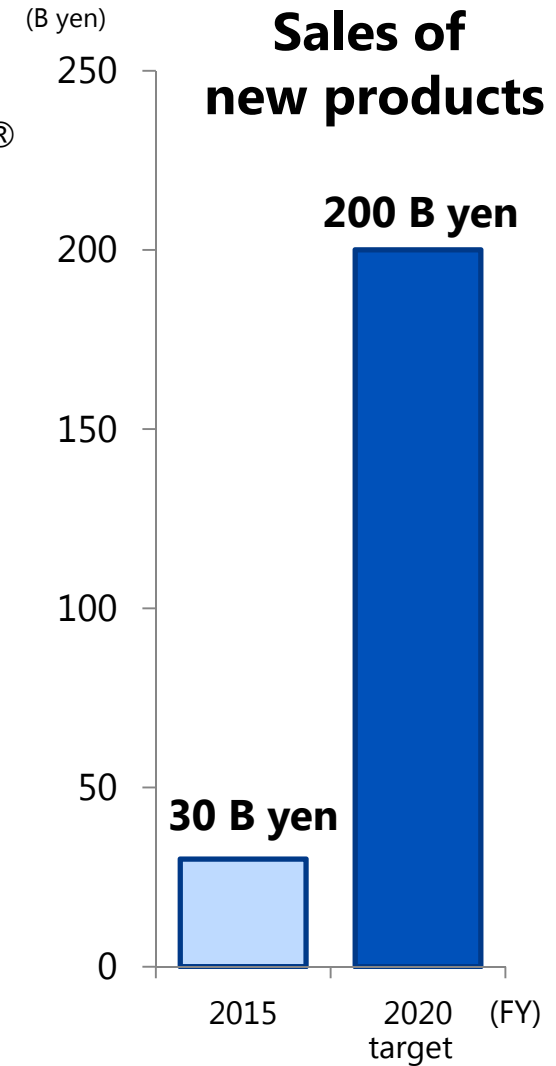
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine
- Guanfacine hydrochloride, lisdexamfetamine

**Infectious
diseases**

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

Others

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



Forward-Looking Statements



- 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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