

3rd Quarter of Fiscal 2015
Financial Results
Conference Call

February 1, 2016

SHIONOGI

Overview of 3rd Quarter FY2015 Financial Results

Summary of Q3 FY2015

- **Sales on track**
  - Increased royalty income from ViiV Healthcare based on the strong growth of HIV franchise
  - Up-front and milestone payments from alliance partners

- **All income levels exceeded our plan and were higher than the levels achieved in the Apr. to Dec. period of any prior fiscal year**
  - Controlled overall costs (SG&A and R&D expenses)
  - Achieved positive operating income, excluding royalties from Crestor® and the HIV franchise, in the Apr. to Dec. period

Financial Results (Consolidated)

(Units: B yen)

	FY2015 forecasts	FY2015 Apr-Dec results	Progress vs. forecasts (%)	FY2014 Apr-Dec results	Y on Y	
					change (%)	change
Sales	301.5	225.9	74.9	200.3	12.8	25.6
Operating income	78.0	65.5	83.9	36.1	81.5	29.4
Ordinary income	88.0	66.5	75.6	51.7	28.7	14.8
Profit attributable to owners of parent	59.0	41.7	70.6	26.3	58.7	15.4

Note: All numerical values are rounded to the nearest unit

- **All income levels are higher than the levels achieved in the Apr. to Dec. period of any prior fiscal year**

Exchange rate (average)	FY2015 forecasts	Apr-Dec results
USD ($) – JPY (¥)	120	121.8
EUR (€) – JPY (¥)	130	134.4
GBP (£) – JPY (¥)	180	186.7

Sales of main merchandise and finished goods (Consolidated)

(Unit: B yen)

	FY2014	FY2015			
	Apr-Dec results	Apr-Dec results	change (%)	Full year forecasts	Progress vs. forecasts (%)
Prescription drugs	120.8	123.4	2.2	167.0	73.9
Crestor®	32.1	33.6	4.5	44.4	75.6
Irbetan® franchise	11.4	12.0	5.6	17.0	70.8
Cymbalta®*	8.5	11.5	36.0	17.4	66.1
Total of 3 key products	52.0	57.1	9.8	78.8	72.5
OxyContin® franchise	8.2	8.0	(2.5)	10.7	74.8
Finibax®	3.0	3.0	(0.7)	3.8	79.1
Differin®	2.9	2.3	(20.9)	3.8	59.6
Pirespa®	4.0	4.6	16.0	5.4	86.1
Rapiacta®	1.1	0.4	(60.4)	2.8	16.0
Total of 8 strategic products	71.2	75.5	6.0	105.3	71.7
Overseas subsidiaries/export**	21.3	22.7	6.6	30.4	74.9
Shionogi Inc.	12.0	13.2	10.3	17.4	76.1
Osphena®	3.1	3.8	20.8	7.4	51.0
Contract manufacturing**	9.9	5.4	(45.9)	7.6	70.0
Royalty income	42.3	68.4	61.4	88.8	77.0
Royalty income for the sales of Crestor® and HIV franchise	36.4	60.7	66.7	80.0	75.9
Crestor®	35.1	35.7	1.6	-	-
HIV franchise	1.3	25.0	-	-	-
Others	6.0	6.1	1.8	7.7	79.0
Total	200.3	225.9	12.8	301.5	74.9

Domestic prescription drugs

- Sales of Crestor® on track after the package change in Q2
- Slow flu season
- Launch of Actair® and Mulpleta®

US business

- Increase in Osphena® Rx
- Divestiture of non-promoted products

Royalty income

- Received up-front and milestone payments
- HIV franchise showed steady growth despite the launch of a new competitor

* Remuneration for promotional activity from FY2015

** The accounting policy for API for dolutegravir was changed from export to contract manufacturing in FY2014

Statements of Income (Consolidated)

(Unit: B yen)

	FY2014	FY2015			
	Apr-Dec results	Apr-Dec results	change (%)	Full year forecasts	Progress vs. forecasts (%)
Sales	200.3	225.9	12.8	301.5	74.9
[Royalty* income]	36.4	60.7	66.7	80.0	75.9
Cost of sales	29.3 [35.9] 58.8	24.4 [33.4] 55.2	(6.1)	24.4 [33.2] 73.5	75.1
Gross profit	141.5	170.7	20.7	228.0	74.9
SG&A expenses	52.6 105.4	46.6 105.3	(0.1)	49.8 150.0	70.2
Selling & general expenses	69.8	70.0	0.2	101.0	69.3
R&D expenses	35.6	35.3	(0.8)	49.0	72.0
Operating income	18.0 36.1	29.0 65.5	81.5	25.9 78.0	83.9
[Excluding royalty* income]	(0.3)	4.8	-	(2.0)	-
Non-operating income and expenses	P15.7	P1.1	(93.1)	P10.0	10.9
Ordinary income	25.8 51.7	29.5 66.5	28.7	29.2 88.0	75.6

Improved cost of sales

- Modification of Cymbalta® contract
- Up-front and milestone payments

Cost management and investment for growth

- Sales activities for Osphena® including DTC campaign
- Strategic investment in R&D utilizing the income from out-licensing deals

Operating income

- Achieved positive operating income excluding royalties* in the Apr. to Dec. period

Non-operating income and expenses

- Received dividends from ViiV Healthcare in Q1 and Q3 FY2014

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
DTC: Direct to consumer

To achieve FY2015 Targets

Key Actions in H2 FY2015

◆ Strengthen Japanese business base

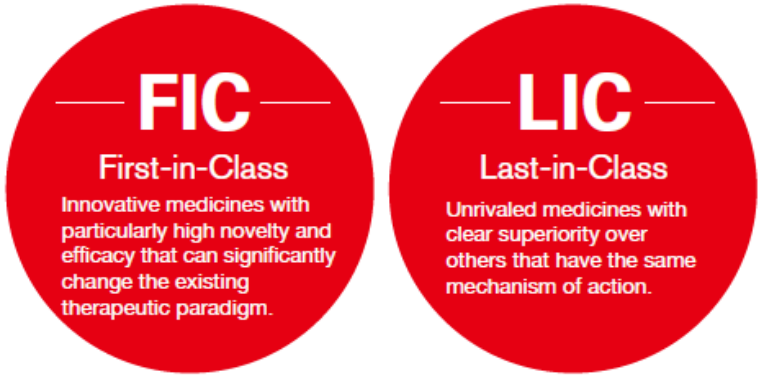
- ➢ Continue to drive increased sales of strategic products
- ➢ Continued growth of Crestor®
- ➢ Strengthening the sales activities in both CNS and Pain areas to maximize the potential of Cymbalta®
- ➢ Launch of Actair® and Mulpleta®

- ● Pre-launch activities for S-877503 (pediatric ADHD)

◆ Strengthening capability to support new global products

- ● Osphena®
  - ➢ Outcomes from efforts to support patient access and DTC outreach
    - • Increased new prescriptions
    - • Decreased the abandonment rate by patients who were prescribed Osphena®
  - ➢ Initiated Phase III clinical study for vaginal dryness to maximize the value of Osphena®
- ● Establishing platform for NDA submission and launch of naldemedine

Research & Development



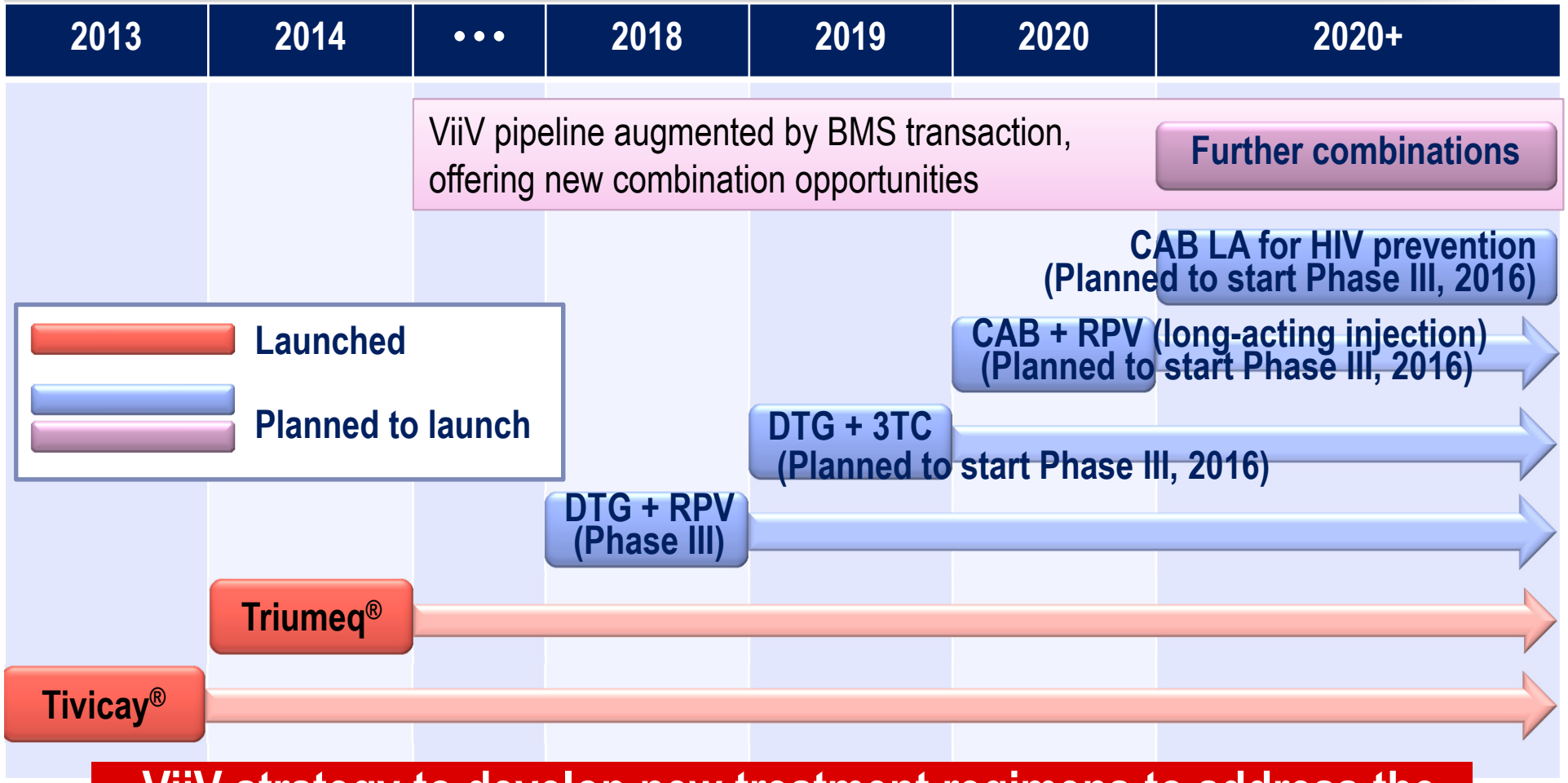
Target Milestones and Progress in FY2015

Areas	Code No.	Indication	Target milestone for FY2015	As of Feb. 2016
Infectious disease	S-649266	Severe Gram-negative infections	Global: Phase III initiated	Global: Phase II & III
	S-033188	Influenza virus infection	Japan: Phase I completed Go/No Go decision	Japan: Phase II
Pain/CNS	Cymbalta®	Pain associated with fibromyalgia	Japan: Approved (May 2015)	
		Pain associated with chronic low back pain	Japan: Approval	NDA submission (Dec. 2014)
		Pain associated with osteoarthritis	Japan: Phase III completed	Japan: NDA submission (in preparation)
	Naldemedine (S-297995)	Opioid-induced constipation	US/Japan: NDA submission	Global: NDA submission (in preparation)
	OxyContin®	Cancer/Non-cancer pain (Abuse deterrent)	Japan: Phase I initiated	
	S-718632	Chronic pain (Abuse deterrent)	US: Decision on final formulation	Cancellation of co-development with Egalet
	S-877503	ADHD (pediatric)	Japan: NDA submission	Japan: NDA submission (Jan. 2016)
		ADHD (adult)	-	Japan: Phase III
Frontier	Mulpleta®	Thrombocytopenia	Japan: Approval (Sep. 2015)	

Blue: Achieved FY2015 target Under line: Changed from Oct. 2015

ADHD: Attention deficit hyperactivity disorder

HIV Integrase Inhibitor Franchise



ViiV 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

Source: GSK disclosure (R&D Day on Nov. 2, 2015 and press release on Dec.18, 2015)
DTG: doluteguravir, RPV: rilpivirine, CAB: cabotegravir, LA: log-acting, BMS: Bristol-Myers Squibb

R&D

Revision of Contract for Cephalosporin Antibiotics

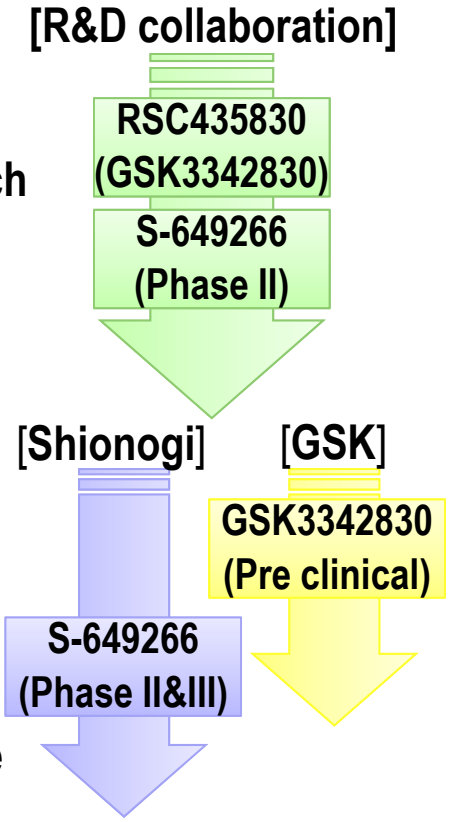
Former contract

- Initiated the research and development collaboration with GSK in 2010
- Focused on development of novel cephalosporins
  - Most advanced compound was S-649266
  - Shionogi received upfront and milestone payments
- Provided for shared costs and profits in certain major markets, while each company had exclusive, royalty-bearing rights in other territories
- Collaboratively discovered RSC435830 (GSK3342830)
  - The profile of RSC435830 is different from S-649266

Revision of Contract in Nov. 2015

Revised contract

- Shionogi will pursue development and commercialization of S-649266 and GSK will pursue development and commercialization GSK3342830 fully independently from the revision
- Shionogi received a payment upon execution of the restated agreement and will receive payments upon achievement of certain milestones in the progression of GSK3342830. Certain royalties will be payable by each party to the other on net sales of their respective compounds



Gram-negative bacterial infections represent a serious problem worldwide, particularly with the increasing prevalence of multi-drug resistant strains. Both companies will focus each resource on their selected compound to accelerate the development

Naldemedine, Cymbalta® and S-877503

◆ Naldemedine

- Indication
  - ➢ Opioid-induced constipation
    Japan, US: NDA submission (in preparation)
    (Planned to NDA submission in FY2015)

◆ Cymbalta® (duloxetine)

- Indication
  - ➢ Pain associated with chronic low back pain:
    Japan: NDA submission (Dec. 2014)
  - ➢ Pain associated with chronic osteoarthritis:
    Japan: NDA submission (in preparation)
    (Planned to NDA submission in FY2015)

◆ S-877503 (alpha2A-adrenergic receptor agonist)

- Indication
  - ➢ ADHD (pediatric): Japan NDA submission (Jan. 2016)
  - ➢ ADHD (adult): Japan Phase III study

ADHD: Attention deficit hyperactivity disorder

R&D

Pipeline for Future Growth in the Japanese Domestic Market

Phase I	Phase II	Phase III	NDA	Approval	Launch
Cymbalta® (Pain associated with fibromyalgia)				Approved: May 2015	
Actair® (Allergic rhinitis caused by house-dust mite allergen)				Launched: Nov. 2015	
Mulpleta® (lusutrombopag) (Thrombocytopenia)				Launched: Dec. 2015	
Cymbalta® (Pain associated with chronic low back pain)			NDA submission: Dec. 2014		
S-877503 (ADHD [pediatric])			NDA submission: Jan. 2016		
Cymbalta® (Pain associated with osteoarthritis)			NDA submission (in preparation)		
Naldemedine (S-297995) (Opioid-induced constipation)			NDA submission (in preparation)		
S-877489 (ADHD [pediatric])					
OxyContin® (Moderate to severe chronic pain; tamper resistant formulation)					
S-649266 (Severe Gram-negative infections)					
S-877503 (ADHD [adult])					
S-033188 (Influenza virus infection)					
S-237648 (Obesity)					

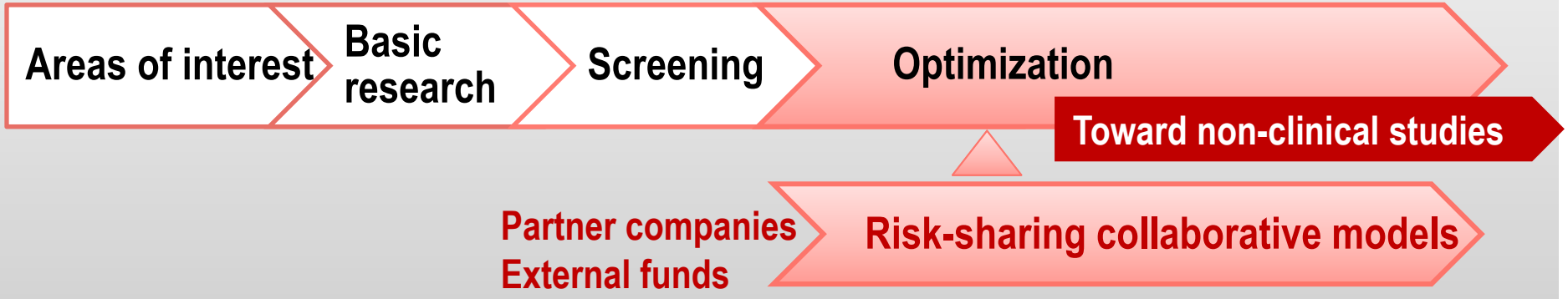
Steady series of launches in the Japanese market

SHIONOGI

Infectious disease | Pain/CNS | Metabolic syndrome | Frontier

Advancing Research Programs through Alliances

Shionogi's established strength in "Small Molecule Drug Discovery-engine"



- Collaborative research on novel pain drugs with Pionnie which was established by OCCI and venture capital (announced in Sep. 2015 by OCCI)
- Collaborative research on novel antifungal drugs with Nissan Chemical Industries, Ltd. (announced in Jan. 2016)

Risk-sharing collaborations efficiently utilizes R&D resources while enhancing our program pipeline

- **Maximally leverage our Small Molecule Drug Discovery-engine**
- **Enrich the drug discovery portfolio**

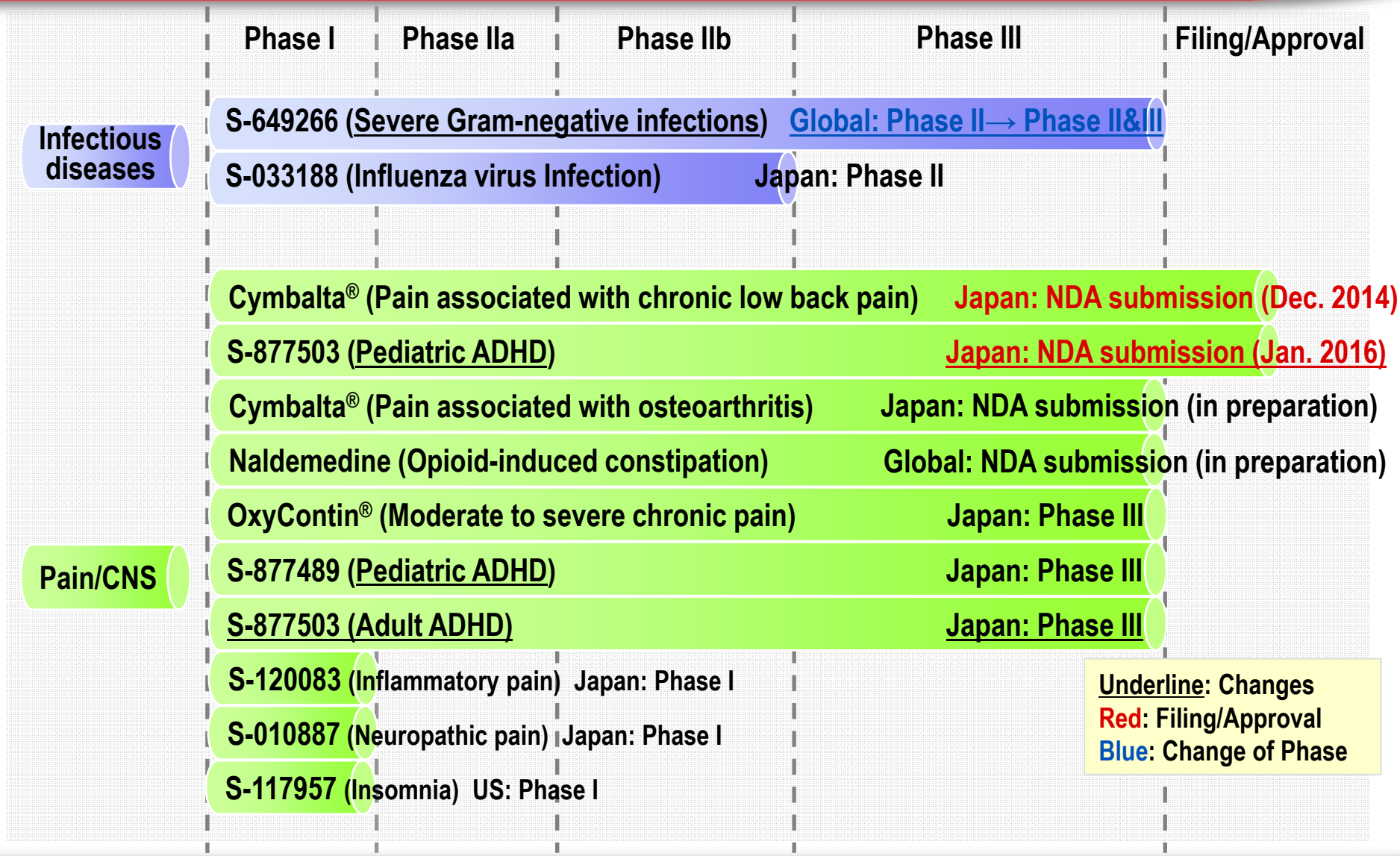
OCCI: Osaka Chamber of Commerce and Industry

Appendix
- Pipeline -

Changes in Pipeline (since Oct. 2015)

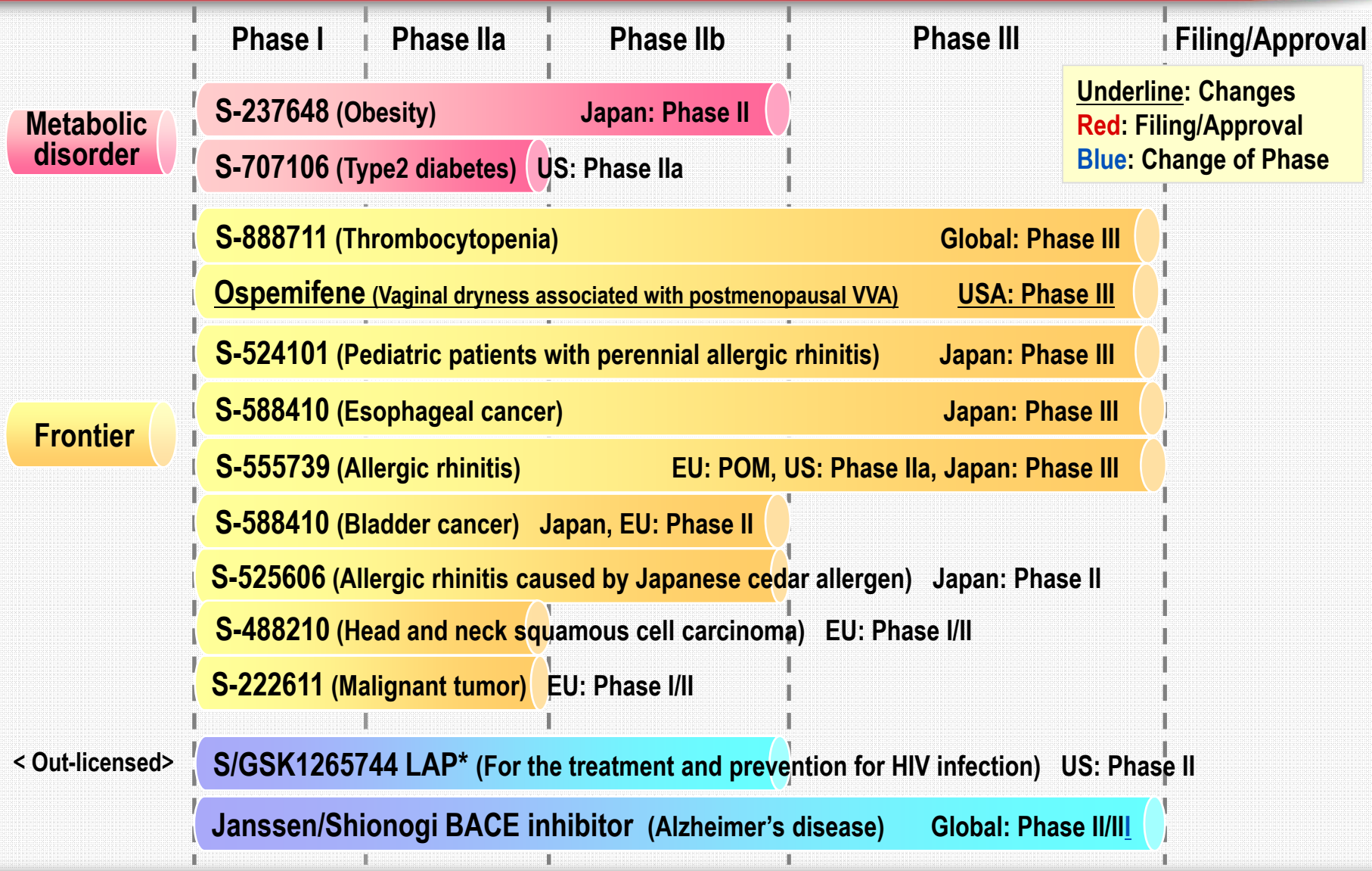
Code No. / Product name	Indication	Phase	Area	Changes
Change of phase				
S-649266	Severe Gram-negative infections	Phase II & III	Global	Severe gram-negative infections → Severe Gram-negative infections Global: Phase II → Global: Phase II & III
S-877503	ADHD (pediatric)	NDA submission (Jan. 2016)	Japan	ADHD → ADHD (pediatric) NDA submission (in preparation) →NDA submission (Jan. 2016)
Compound added to the list				
Ospemifene	Vaginal dryness associated with postmenopausal VVA	Phase III	USA	
S-877503	ADHD (adult)	Phase III	Japan	

Pipeline (as of Feb. 2016)



ADHD: Attention deficit hyperactivity disorder

Pipeline (as of Feb 2016)



* Licensed out to ViiV Healthcare

POM: Proof of mechanism
LAP: Long acting parenteral formulation

Appendix
- Financial results -

Japan: Sales of 8 Strategic Products

(Units: B yen)

	FY2015		Progress vs. forecasts (%)	FY2014	Y on Y		FY2015	FY2014	Y on Y change (%)
	2H forecasts	Oct-Dec results		Oct-Dec results	change (%)	change	Apr-Dec results	Apr-Dec results	
Prescription drugs	88.6	45.0	50.8	43.8	2.7	1.2	123.4	120.8	2.2
Crestor®	24.0	13.2	54.9	11.1	18.8	2.1	33.6	32.1	4.5
Irbetan® franchise	8.7	3.7	42.7	3.9	(4.0)	(0.2)	12.0	11.4	5.6
Cymbalta®*	10.2	4.3	42.2	3.0	44.0	1.3	11.5	8.5	36.0
Total of 3 key products	42.9	21.2	49.4	17.9	18.1	3.3	57.1	52.0	9.8
OxyContin® franchise	5.5	2.8	51.3	2.9	(2.7)	(0.1)	8.0	8.2	(2.5)
Finibax®	1.7	0.9	53.3	1.1	(17.5)	(0.2)	3.0	3.0	(0.7)
Differin®	2.2	0.7	31.6	1.1	(33.3)	(0.4)	2.3	2.9	(20.9)
Pirespa®	2.6	1.9	71.5	1.4	35.1	0.5	4.6	4.0	16.0
Rapiacta®	2.8	0.5	16.1	1.1	(58.3)	(0.6)	0.4	1.1	(60.4)
Total of 8 strategic products	57.8	28.0	48.4	25.5	9.7	2.5	75.5	71.2	6.0
[percent of sales]	65.3%	62.3%		58.2%			61.2%	59.0%	

* Remuneration for promotional activity from FY2015

Sales of main merchandise and finished goods (Consolidated)

(Units: B yen)

	FY2015		Progress vs. forecasts (%)	FY2014	Y on Y		FY2015	FY2014	Y on Y change (%)
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Prescription drugs	88.6	45.0	50.8	43.8	2.7	1.2	123.4	120.8	2.2
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Total of 8 strategic products	57.8	28.0	48.4	25.5	9.7	2.5	75.5	71.2	6.0
Overseas subsidiaries/export*	15.7	8.0	51.2	7.5	6.5	0.5	22.7	21.3	6.6
Shionogi Inc.	9.0	4.8	53.7	4.6	5.1	0.2	13.2	12.0	10.3
Osphena®	4.8	1.2	24.8	1.4	(16.8)	(0.2)	3.8	3.1	20.8
C&O	4.7	1.3	28.5	1.7	(24.1)	(0.4)	4.7	5.0	(7.1)
Contract manufacturing*	3.9	1.6	41.9	3.0	(45.4)	(1.4)	5.4	9.9	(45.9)
OTC and quasi-drugs	2.1	1.2	58.4	1.2	5.2	0.0	3.8	3.6	5.0
Royalty income	51.3	30.9	60.2	14.0	120.0	16.9	68.4	42.3	61.4
Royalty income for the sales of Crestor® and HIV franchise	45.0	25.7	57.1	12.0	113.4	13.7	60.7	36.4	66.7
Crestor®	-	12.0	-	10.7	12.0	1.3	35.7	35.1	1.6
HIV franchise	-	13.7	-	1.3	-	12.4	25.0	1.3	-
Others	1.6	0.9	54.1	0.8	1.9	0.1	2.3	2.3	(3.1)
Total	163.2	87.6	53.7	70.4	24.4	17.2	225.9	200.3	12.8

Eight strategic products: Crestor®, Irbetan® franchise, Cymbalta® (3 key products), and OxyContin® franchise, Finibax®, Differin®, Pirespa®, Rapiacta®

* The accounting policy for API for dolutegravir was changed from export to contract manufacturing in FY2014

Statements of Income (Consolidated)

(Units: B yen)

	FY2015		Progress vs. forecasts (%)	FY2014	Y on Y		FY2015	FY2014	Y on Y change (%)
	2H forecasts	Oct-Dec results		Oct-Dec results	change (%)	change	Apr-Dec results	Apr-Dec results	
Sales	163.2	87.6	53.7	70.4	24.4	17.2	225.9	200.3	12.8
[Royalty* income]	45.0	25.7	57.1	12.0	113.4	13.7	60.7	36.4	66.7
Cost of sales	22.7 [31.3] 37.0	21.4 [30.2] 18.7	50.5	29.3 [35.3] 20.6	(9.2)	(1.9)	24.4 [33.4] 55.2	29.3 [35.9] 58.8	(6.1)
Gross profit	126.2	68.9	54.6	49.8	38.4	19.1	170.7	141.5	20.7
SG&A expenses	50.3 82.1	42.7 37.4	45.5	51.8 36.5	2.6	0.9	46.6 105.3	52.6 105.4	(0.1)
Selling & general expenses	54.9	23.9	43.6	24.1	(0.5)	(0.2)	70.0	69.8	0.2
R&D expenses	27.2	13.5	49.6	12.4	8.6	1.1	35.3	35.6	(0.8)
Operating income	27.0 44.1	36.0 31.5	71.5	19.0 13.3	136.2	18.2	29.0 65.5	18.0 36.1	81.5
[Excluding royalty* income]	(0.9)	5.9	-	1.3	342.2	4.6	4.8	(0.3)	-
Non-operating income and expenses	P9.1	P0.2	2.5	P7.0	(96.7)	(6.8)	P1.1	P15.7	(93.1)
Ordinary income	32.6 53.2	36.2 31.8	59.7	28.8 20.3	56.4	11.5	29.5 66.5	25.8 51.7	28.7
Extraordinary income and loss	L0.0	L1.1	-	P4.3	-	(5.4)	L1.3	P4.5	-
Income before income taxes	53.2	30.6	57.5	24.6	24.6	6.0	65.3	56.2	16.1
Total income taxes, etc.	15.6	10.3	66.2	8.0	28.9	2.3	23.6	30.0	(21.3)
Profit attributable to owners of parent	23.0 37.6	23.1 20.3	53.9	23.5 16.6	22.5	3.7	18.4 41.7	13.1 26.3	58.7

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

Appendix
- SGS2020 -

SHIONOGI's Strategy

SHIONOGI's medium-term business plans since 2000

	Clear priorities and focused resourcing	Growth strategy
1st mid-term business plan (FY2000-FY2004)	Focused specifically on the prescription drug business	Established infrastructure for global development
2nd mid-term business plan (FY2005-FY2009)	Focused on Priority therapeutic areas (infectious diseases, pain and metabolic syndrome	Acquired US-based Sciele Pharma, Inc.
3rd mid-term business plan (FY2010-FY2013)	In Japan, increased sales of eight strategic products Shifted US business focus from 505(b)2s to innovative drugs	Established business footholds in EU and China Modified the Crestor® royalty structure Established a new business scheme for HIV integrase inhibitor franchise
Current mid-term business plan SGS2020 (FY2014-FY2020)	Focus on regions with the highest growth potential Focus on unmet medical needs of the present, near future and future	Growth led by FIC and LIC compounds Accelerate development our pipelines discovered from Shionogi's R&D Developing better relationship with business partners Enhancement of business operations

- Predicting the future from environmental changes and continuing clear priorities and focused resourcing
- Set the business targets in the next three years for sustainable growth by clarifying annual results and business status each year on a rolling basis

FIC: First-in-Class, LIC: Last-in-Class

Revision of FY2015 Financial Forecasts

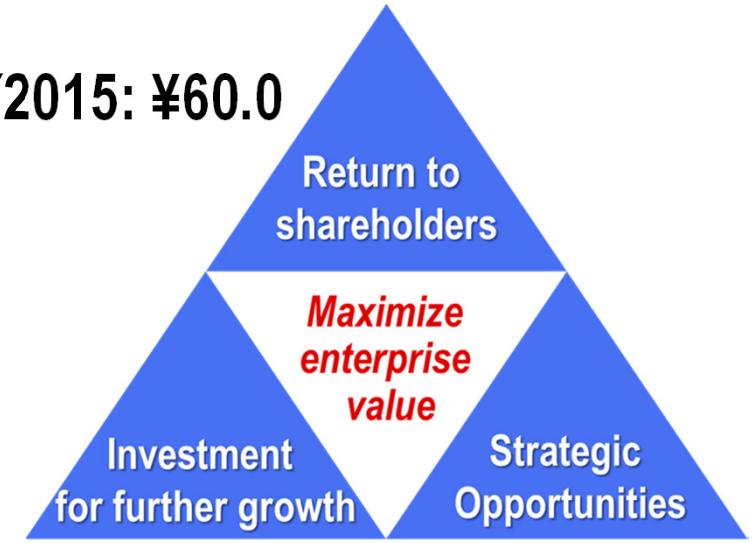
Favorable progress toward achieving FY2017 targets

	FY2014 (Results)	FY2015 (Forecasts) Revised on Oct. 29	FY2017 (Targets*)
Net sales	274.0 B yen	296.0 ⇨ 301.5 B yen	350.0 B yen
Cost of sales	30.0 %	24.8 ⇨ 24.4 %	25 %*
Ordinary income	77.9 B yen	79.5 ⇨ 88.0 B yen	90.0 B yen
ROE	9.4 %	10.6 ⇨ 11.9 %	12.0 %

* Target for cost of sales for FY2020

Financial Strategy in SGS2020

- **Financial Strategy: Business operation focusing capital efficiency (Setting ROE target)**
  - Share holder returns
    - Steady increase in dividends
      - ✓ Plan to full-year dividend for FY2015: ¥60.0
    - Flexible share buyback
  - Investment for further growth
  - Strategic business opportunities



Balancing three key factors to maximize the enterprise value by Utilizing incomes from the evolution of core businesses

SGS2020 Rolling Plan (Targets for FY2017)

Targets for FY2017 - the next rolling three-year period of SGS2020

FY2015	FY2016	FY2017	FY2018	FY2019	FY2020

Clear priorities and focused resourcing

Evolution of Core Business

Net sales 350 B yen
Ordinary income 90 B yen
ROE 12%

Growth led by FIC and LIC compounds

Shift Gears for Growth

Net sales 500 B yen
Ordinary income 125 B yen
ROE 15%

Clarify annual results and business status in three-year rolling plans

FY2015 to FY2017: Advancing core businesses and positioning for further growth

- Maximize the value of Crestor® and Cymbalta® in Japan
- Increase revenues from Osphena® in the US
- Strengthen pipeline in our core therapeutic areas
- Develop an operating structure independent of royalty income

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.
- Materials and information provided during this presentation may contain so-called “forward-looking statements”. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.
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