



SGS2020

The Growth Strategy of Shionogi

December 2, 2015

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President and CEO**



Rapidly-aging global society

- ◆ Increasing, but increasingly segmented, medical needs
- ◆ Increased expectations for efficacy and safety of new drugs
- ◆ Growing expectations healthy life expectancy
- ◆ Increasing trends toward self medication

Expanding range of therapeutic agents to include new drug discovery paradigms

- ◆ Applying innovative technologies such as iPS cells to enable regenerative medicine and new drug discovery
- ◆ Shifting to precision medicine*, targeting therapy based on individual factors such as genetic background, environment and lifestyle

Changes in the Japanese and global pharmaceutical markets

- ◆ Developed countries: Financial pressure on health insurance, controversy around high drug prices, both adding to pricing pressure
- ◆ Emerging countries: Slowdown in economic growth, political risk to drug pricing, intellectual property risk

Enhanced expectations for the pharmaceutical industry in Japan

- ◆ Contribution to economic growth as a high value-added industry
- ◆ Strategic industry supported by the government

Stages 1 through 3: FY2000 - FY2013



1st stage: Laying the foundation (FY2000 - 2004)

- ◆ Focused specifically on the prescription drug business
- ◆ Established infrastructure for global development

2nd stage: Accelerating toward significant strides (FY2005 - 2009)

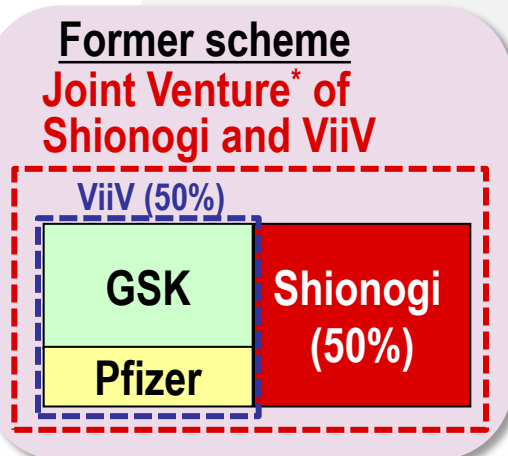
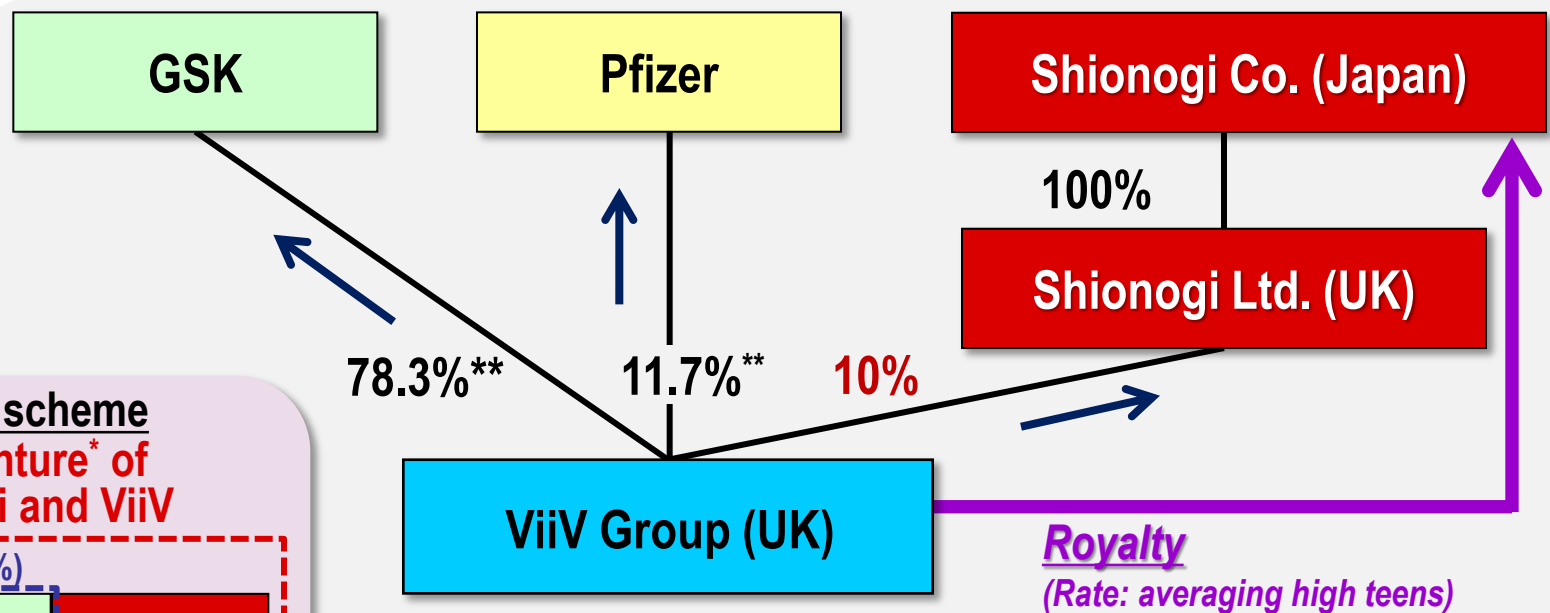
- ◆ Focused R&D efforts on priority therapeutic areas (infectious diseases, pain, and metabolic syndrome)
- ◆ Acquired US-based Sciele Pharma, Inc.

3rd stage: SONG for the Real Growth (FY2010 - 2013)

- ◆ Shifted US business focus from 505(b)2s to innovative drugs while stabilizing business performance, and established business footholds in EU and China
- ◆ In Japan, increased sales of eight strategic products, and expanded their share of Rx sales
- ◆ Launched Tivicay[®] and Osphena[®]
- ◆ Established a new business scheme for HIV integrase inhibitor franchise
- ◆ Modified the Crestor[®] royalty structure

Stable Earnings from HIV Integrase Inhibitor Portfolio

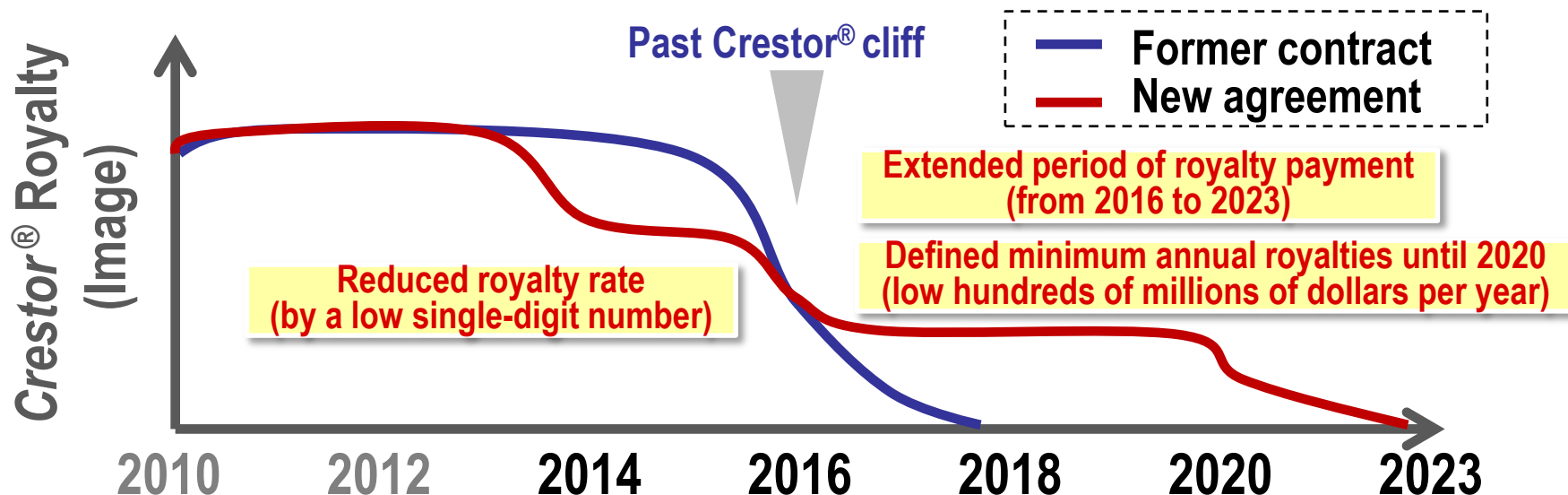
- ◆ New arrangement with ViiV Healthcare Ltd. (announced on Oct. 29, 2012)
 - JV's rights* to the integrase inhibitor franchise products were transferred to ViiV, and Shionogi became a 10% shareholder with Board representation



→: Dividends
(FY2014: £37M + £10M+ £70.5M)

Modification of the Crestor® Royalty Structure

◆ New license agreement with AstraZeneca (announced on Dec. 25, 2013)



Crestor®	2010	2011	2012	2013	2014
Global sales (B\$)	5.7	6.6	6.3	5.6	5.5
Royalty income (M\$*)	729	810	791	682	456

New Medium-Term Business Plan of SHIONOGI

Shionogi Growth Strategy 2020 **(SGS2020)**

(Announced on Mar. 28, 2014)

Our Vision

**Grow as a drug discovery-based
pharmaceutical company**

Needs of a rapidly-aging society

(extension of HALE, support return to productive activities)

Sales area

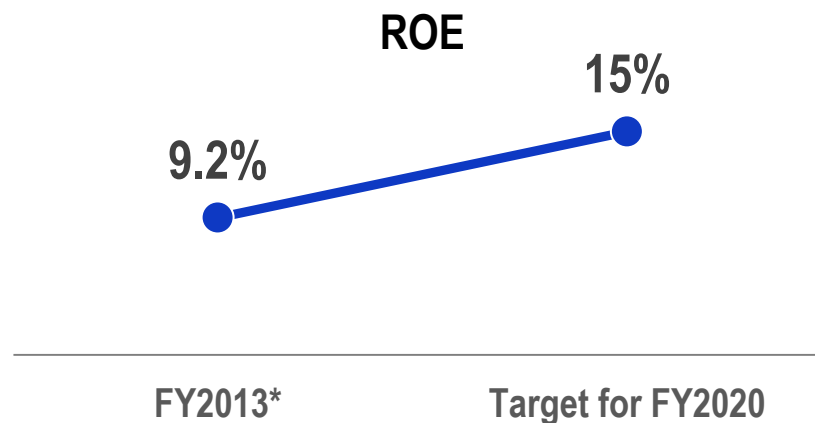
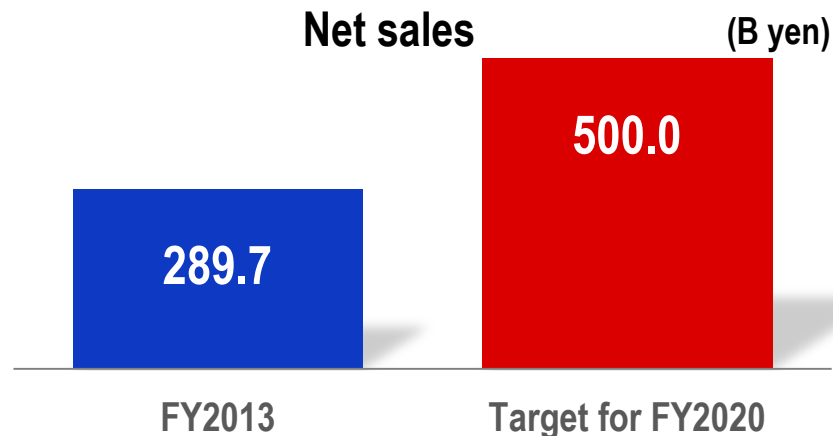
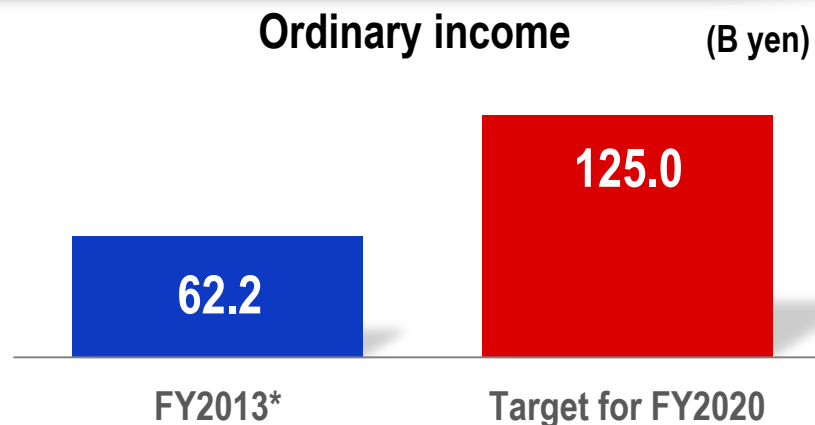
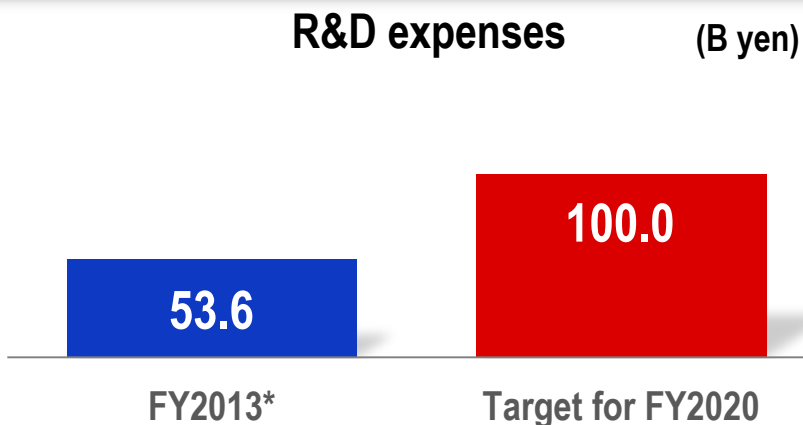
- Japanese market
- US market

Therapeutic area (pipeline)

- Small molecule drug discovery
- Infectious disease
- Pain/CNS

Sales and therapeutic areas chosen based on our strengths and the needs of society

Consolidated Financial Target in SGS2020



Response to rapid environmental changes
(Three-year rolling; Clarify annual results and business challenges)

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

Growth led by FIC and LIC compounds

Shift Gears for Growth

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

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

Revision of FY2015 Financial Forecasts

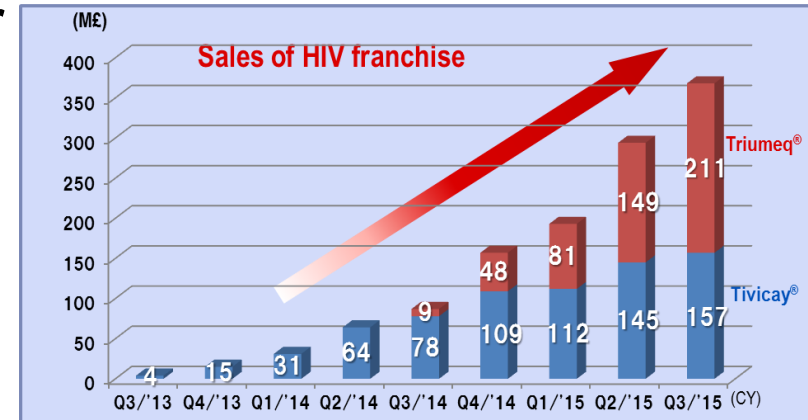


Favorable progress toward achieving FY2017 targets

	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 %	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 %

◆ Demonstrated drug discovery capabilities for anti-infectives

- Tivicay® was discovered via collaborative research and development with ViiV (former Shionogi-GlaxoSmithKline joint venture)
- Triumeq® is a single-pill regimen containing dolutegravir
- Approval: Tivicay® : **US (Aug. 12, 2013)**
Triumeq® : **US (Aug. 22, 2014)**
EU, Canada, Japan, etc.
- Launched by a highly experienced team at ViiV, a global specialist HIV company
- Characteristics: Oral tablet, once-daily



◆ Tivicay, with its **Strong Efficacy and Safety Profile** confirmed in Phase III/IV studies, is an important new option for all lines of HIV treatment

- Tivicay can be used in treatment-naïve and treatment-experienced patients
- In addition to the US NIH Guidelines' recommendation for both Triumeq® and Tivicay® plus Truvada® as the highest rating for ART-naïve patients; WHO recommended ART to be initiated in HIV patients immediately after diagnosis

HIV Integrase Inhibitor Franchise



Phase I	Phase II	Phase III	NDA	Approval	Launch
Tivicay® (dolutegravir)					
Triumeq® (dolutegravir/abacavir/lamivudine)					
Dolutegravir + lamivudine			Out-licensed to ViiV		
Dolutegravir + rilpivirine			Co-development of ViiV and Janssen		
Cabotegravir LA + rilpivirine LA					

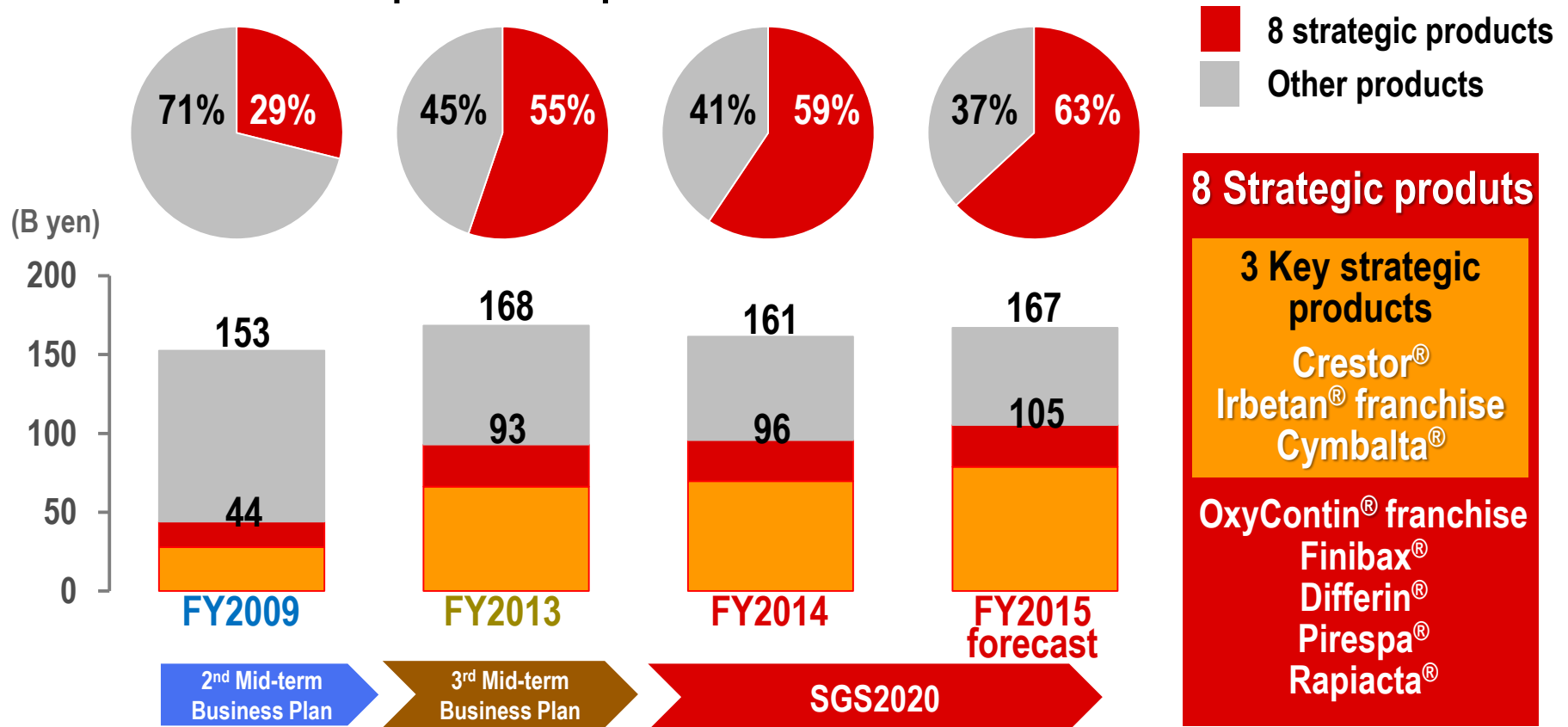
- ◆ **Development of oral fixed dose combination tablet of dolutegravir (DTG) and rilpivirine (RPV) for HIV treatment**
 - Two drug combination therapy leveraging DTG's efficacy, safety and resistance profile
 - Phase III study ongoing: Planned launch H1 2018
- ◆ **Development of oral fixed dose combination tablet of DTG and lamivudine (3TC)**
 - 2-drug STR for treatment in naïve and suppressed patients : Planned launch H1 2019
- ◆ **Development of long-acting injectable cabotegravir (CAB)**
 - CAB + RPV, treatment for HIV infection :Long-acting injectable formulation is expected to reduce the mental burden on patients who otherwise would take their anti HIV agent everyday
 - Phase IIb study ongoing: Planned Phase III start Mid-2016, launch 2019/2020
 - CAB monotherapy for HIV prevention
 - Phase IIa study ongoing: Planned Phase III start 2016 , launch +2020

Sales Growth of Strategic Products in Japanese Market



◆ Increase sales of eight strategic products by improving sales force impact

- Increase profitability by deploying SG&A funds in a new way
- Blunt the impact of NHI price revisions



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® House Dust Mite Sublingual Tablets (Allergic rhinitis caused by house-dust mite allergen)				Approved: Mar. 2015	
Mulpleta® (lusutrombopag) (Thrombocytopenia)				Approved: Sep. 2015	
Cymbalta® (Pain associated with chronic low back pain)			NDA submission: Dec. 2014		
S-877503 (ADHD)			NDA submission (in preparation)		
Cymbalta® (Pain associated with osteoarthritis)			NDA submission (in preparation)		
Naldemedine (S-297995) (Alleviation of opioid-induced adverse effects)			NDA submission (in preparation)		
S-877489 (ADHD)					
OxyContin® (Moderate to severe chronic pain; tamper resistant formulation)					
S-649266 (Severe gram-negative infections)					
S-033188 (Influenza virus infection)					
S-237648 (Obesity)					

Steady series of launches in the Japanese market

**Steady
series of
launches
in the
Japanese
market**



SHIONOGI



Infectious disease



Pain/CNS



Metabolic syndrome



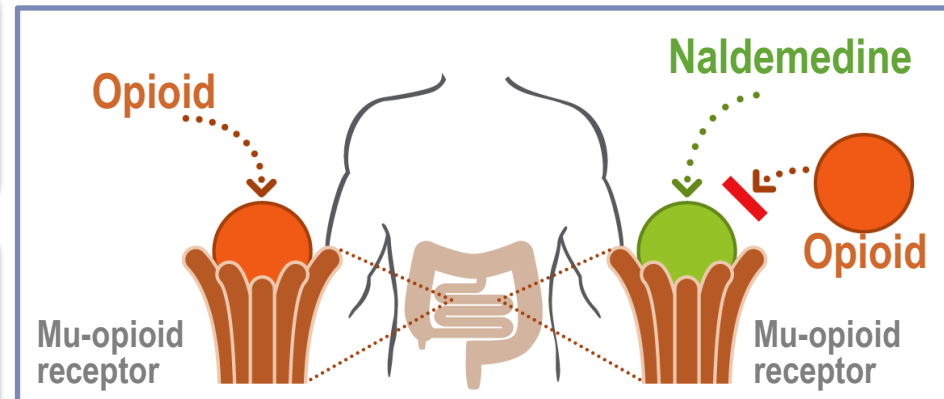
Frontier

Phase I	Phase II	Phase III	NDA	Approval	Launch
Naldemedine (Alleviation of opioid-induced adverse effects) : Global NDA submission (in preparation)					

◆ Mechanism of action of naldemedine on opioid induced constipation (OIC)

Opioids provide analgesia as well as act on peripheral opioid receptors. The latter action in the GI tract causes dysmotility and constipation

Naldemedine is a PAMORA that targets peripheral mu-opioid receptors. In the GI tract, this directly blocks opioid effects on the bowel



OIC: Opioid Induced Constipation

PAMORA: Peripherally-Acting Mu-Opioid Receptor Antagonists

◆ Naldemedine market

- Global opioid market*: US\$14.8B
- Chronic opioid patients 70M (US, UK, Germany, France and Canada)
- 40~90%** of chronic opioid patients experience OIC, and <50% of patients taking laxative report satisfactory results

Infectious Diseases: S-649266, S-033188



Phase I	Phase II	Phase III	NDA	Approval
[Severe gram-negative infections, Global] S-649266				
[Influenza virus infection, Japan] S-033188				

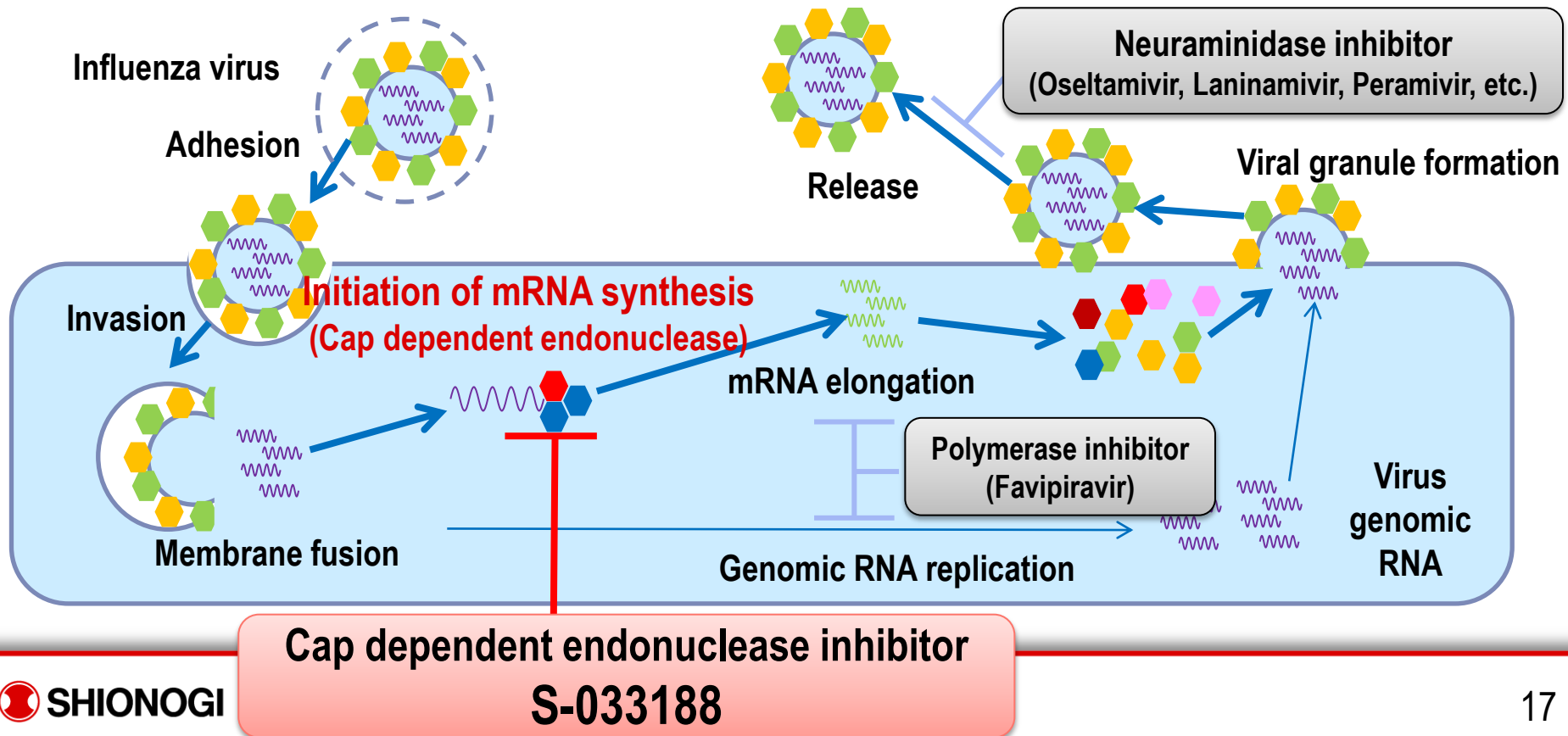
◆ S-649266 (Severe gram-negative infections, injection)

- Novel antibiotic for severe gram-negative infections which shows a unique transport mechanism for uptake into bacterial cells
- Global: Plan to start Phase III study in FY2015

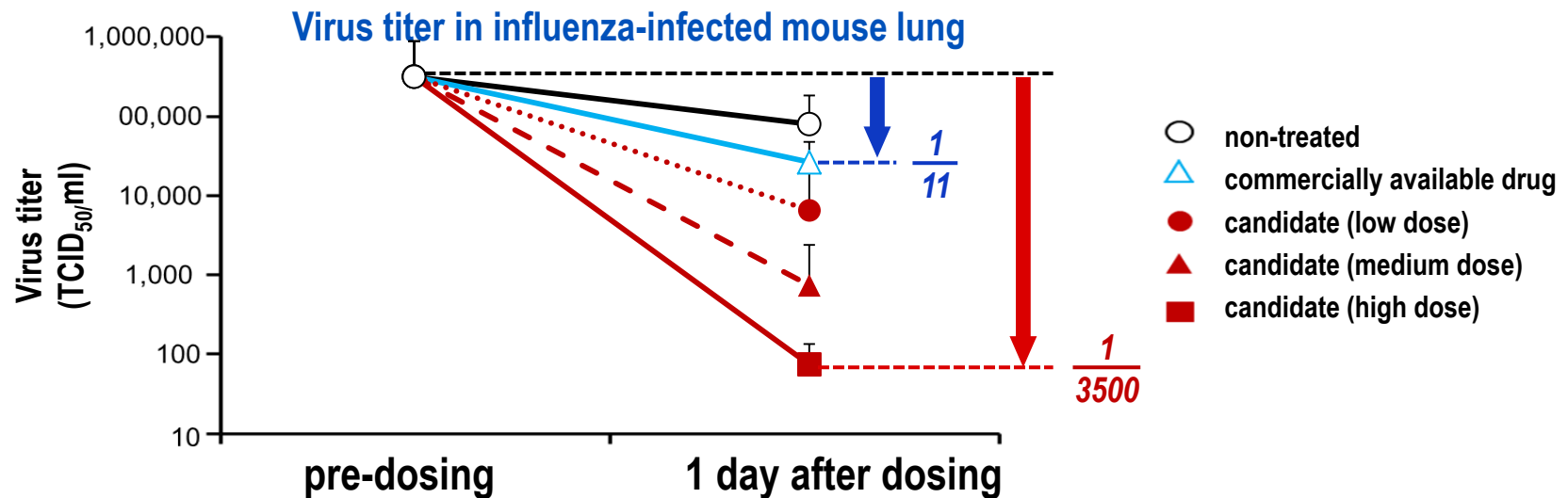
◆ S-033188 (Influenza virus infection, oral)

- Novel mechanism of action (distinct from neuraminidase inhibitors)
- Showed potent *in vitro* inhibitory activity against both influenza A virus, including highly pathogenic bird influenza strains, and influenza B virus
- Target of one time, one dose therapy
- Safety and PK profile confirmed in Phase I study
- Designated for “**priority review system**” on Oct. 27 by the MHLW
 - The review period will be shortened and it will also be given priority for NHI drug price assessment
- NDA submission in Japan in FY2017, as early as possible

- ◆ New drug candidate for Influenza virus infection with novel mechanism of action
 - **Inhibit initiation of mRNA synthesis** which is the first proliferation step after entry of the influenza virus into the cell → "Cap dependent endonuclease inhibitor"
 - Inability to produce proteins essential for virus proliferation inhibits viral granule formation



- ◆ Applying our know-how in anti-viral drug discovery to discover an oral anti-flu drug candidate, aiming at “innovative First-in-Class”
 - **Much greater decline in viral load** in a mouse model compared to that achieved with a commercially-available comparator
 - Showed potent in vitro inhibitory activity against both seasonal and highly pathogenic bird influenza strains resistant to a commercially-available comparator



Expanding and applying our knowledge base built in anti-HIV drug discovery to other viral infections

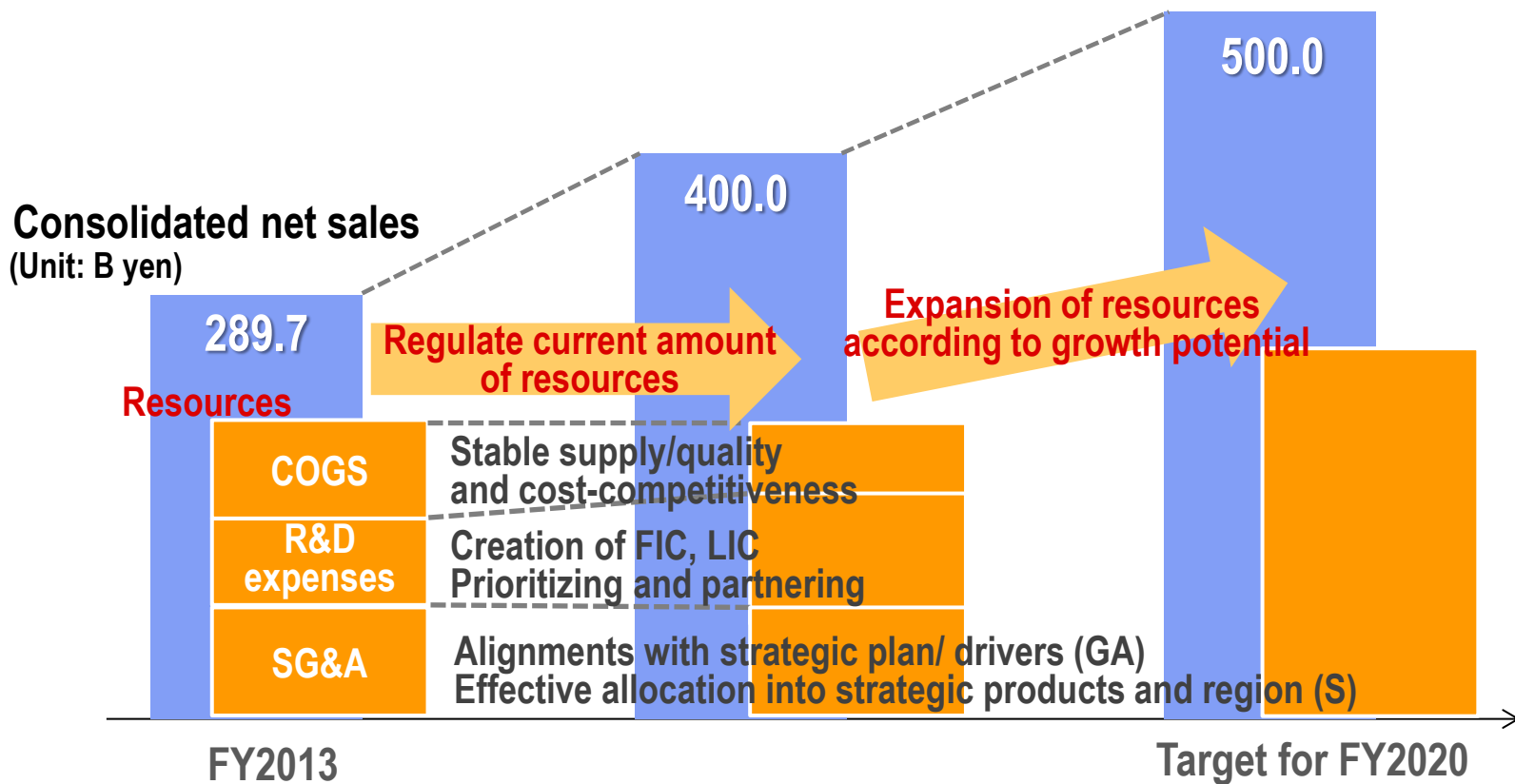
The Medium-Term Business Plan - **Shionogi Growth Strategy 2020**

Continued Improvement of Business Operations

Continued Enhancement of Business Operations



- Resource level to be aligned to growth stage
- Strategic resource allocation



◆ Focus on achieving positive operating income excluding royalties from Crestor® and the HIV franchise

Corporate Value

Value creation for all of stakeholders
and business growth

FIC, LIC compounds

Clear priorities and focused resourcing
Sales areas: Japan and the US
Core therapeutic areas:
Infectious disease and pain/CNS

Crestor®
HIV franchise

Value creation for all stakeholders

Strengthen pipeline in core therapeutic areas
(*Scientific Innovation*)

Positive operating income excluding Crestor® and HIV
(*Business Innovation*)

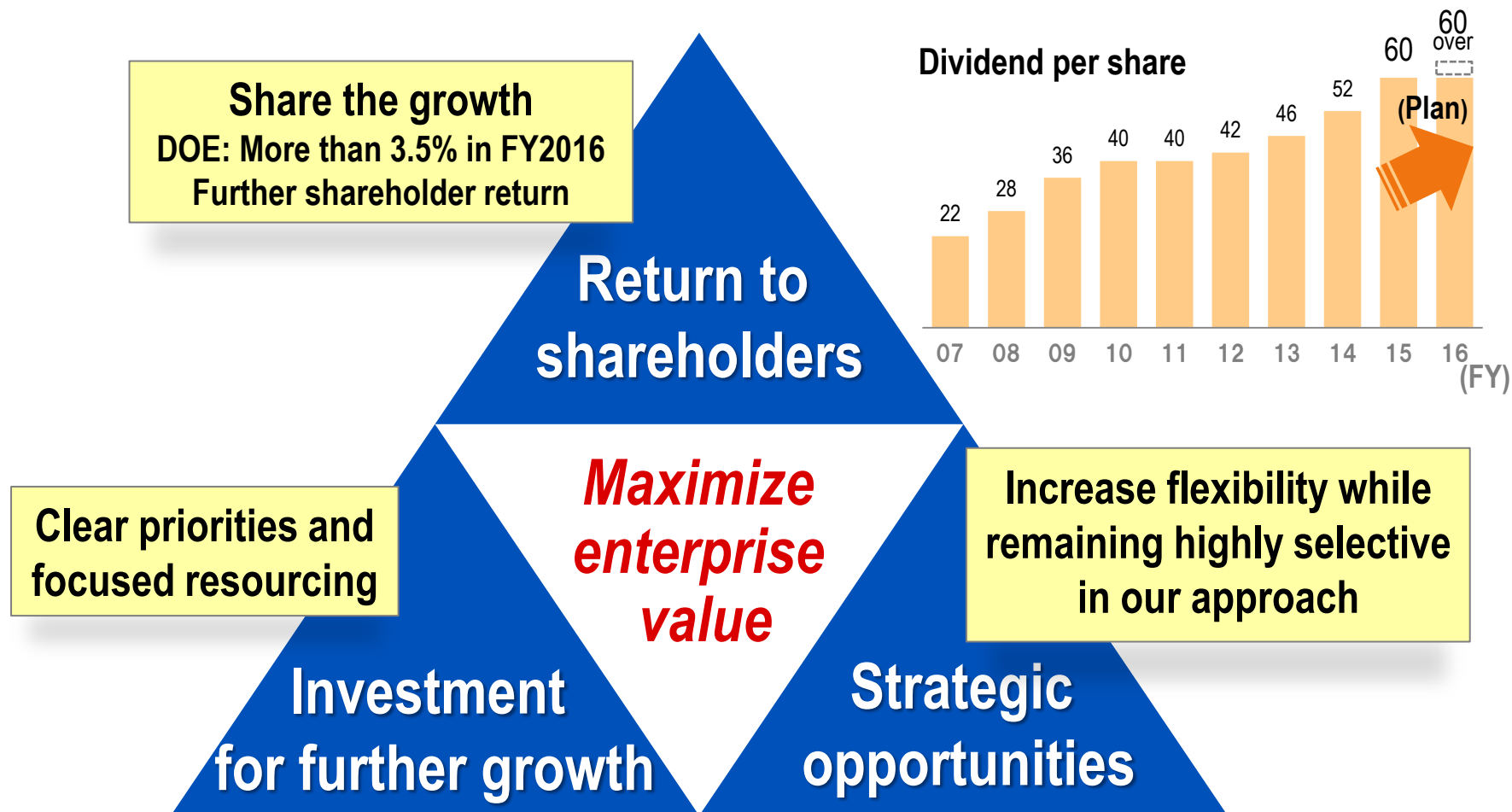
Steady income growth from HIV franchise
Stable Crestor® royalty income



The Medium-Term Business Plan - **Shionogi Growth Strategy 2020**

Shareholder Return and Investment for Our Future

Maximize enterprise value by balancing three key factors

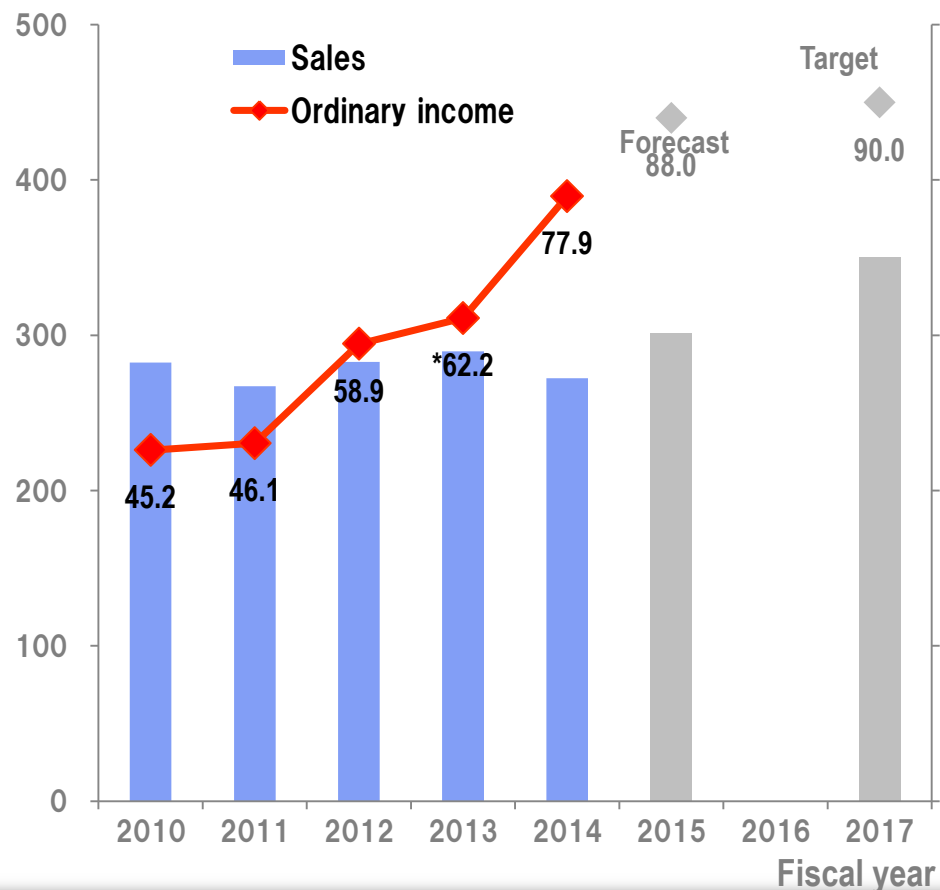


Reaching the Targets Set for FY2017



Steady growth after modifying the Crestor[®] royalty structure

(Sales: B yen)



(Ordinary income: B yen) (ROE:%)



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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