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for you!

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歌が人々を励まし、元気づけてきたように  
くすりも人々の心とカラダを立ちならせてきたように  
歌とくすりは、どちらも人を癒すチカラを  
もっているとおもいます。

誰もが明るくすこやかに暮らすことのために  
私たちは、これからもより良いくすりをつくってきたい。  
そんな想いをこめて、あなたのために。  
SONG for you. シオノギ製薬です。

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# Presentation of Fiscal 2004 Financial results

May 18, 2005

Shionogi & Co., Ltd..  
President Motozo Shiono

 SHIONOGI & CO., LTD.



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# Financial Highlights

## (Consolidated & Non-consolidated)

Billions of yen < Consolidated >	FY04	FY03	% Change FY04/FY03
Sales	199.3	200.4	(0.6)
Operating income	28.7	20.2	41.6
Ordinary income	27.8	17.5	58.1
Net income	18.9	2.2	759.6
<b>&lt; Non-consolidated &gt;</b>			
Sales	180.7	183.2	(1.4)
Operating income	24.5	16.1	52.0
Ordinary income	25.4	15.4	65.0
Net Income	17.7	1.3	-



## Sales by Segment (Consolidated)

	Billions of yen			
	FY04	FY03	Increase/ (Decrease)	% Change FY04/FY03
<b>Ethical Drugs</b>	<b>168.0</b>	<b>173.4</b>	<b>(5.4)</b>	<b>(3.1)</b>
Flomox	33.2	34.5	(1.3)	(3.7)
Flumarin	17.0	19.3	(2.3)	(11.9)
Vancomycin	16.1	18.2	(2.1)	(11.5)
Imunace	10.4	9.5	0.9	9.3
Claritin	8.9	5.5	3.4	62.8
MS Contin	5.6	7.7	(2.1)	(27.7)
Oxycontin	2.9	0.9	2.0	239.5
<b>OTC products</b>	<b>6.3</b>	<b>6.7</b>	<b>(0.4)</b>	<b>(5.9)</b>
<b>Diagnostics</b>	<b>3.5</b>	<b>3.7</b>	<b>(0.2)</b>	<b>(5.7)</b>
<b>Royalty income</b>	<b>6.1</b>	<b>1.2</b>	<b>4.9</b>	<b>393.5</b>
Crestor	4.8	0.7	4.1	580.4
<b>Capsule business</b>	<b>11.8</b>	<b>11.4</b>	<b>0.4</b>	<b>4.1</b>
<b>Industrial chemicals</b>	<b>0.0</b>	<b>0.9</b>	<b>(0.9)</b>	<b>-</b>
<b>Real estate/Logistics</b>	<b>3.3</b>	<b>2.8</b>	<b>0.5</b>	<b>19.8</b>
<b>Total</b>	<b>199.3</b>	<b>200.4</b>	<b>(1.1)</b>	<b>(0.6)</b>

\* Sales of ethical drugs are shown on a non-consolidated basis.



# Cost of Sales, SG&A and Operating Income

	Billions of yen			
	FY04 Results	FY03 Results	% Change	Increase (Decrease)
Sales	199.3	200.4	(0.6)	(1.1)
[Royalty]	[6.1]	[1.2]	390.7	[4.9]
	37.2 [38.3]	39.8 [40.1]		
Costs of sales	74.0	79.8	(7.2)	(5.8)
	48.4	50.1		
SG&A	96.5	100.3	(3.8)	(3.7)
Sales & General research & Development	67.1	70.5	(4.8)	(3.3)
	29.4	29.8	(1.3)	(0.4)
	14.4	10.1		
Operating income	28.7	20.2	41.6	8.5

Note: figures in parenthesis show percentage of cost of goods against sales excluding royalty



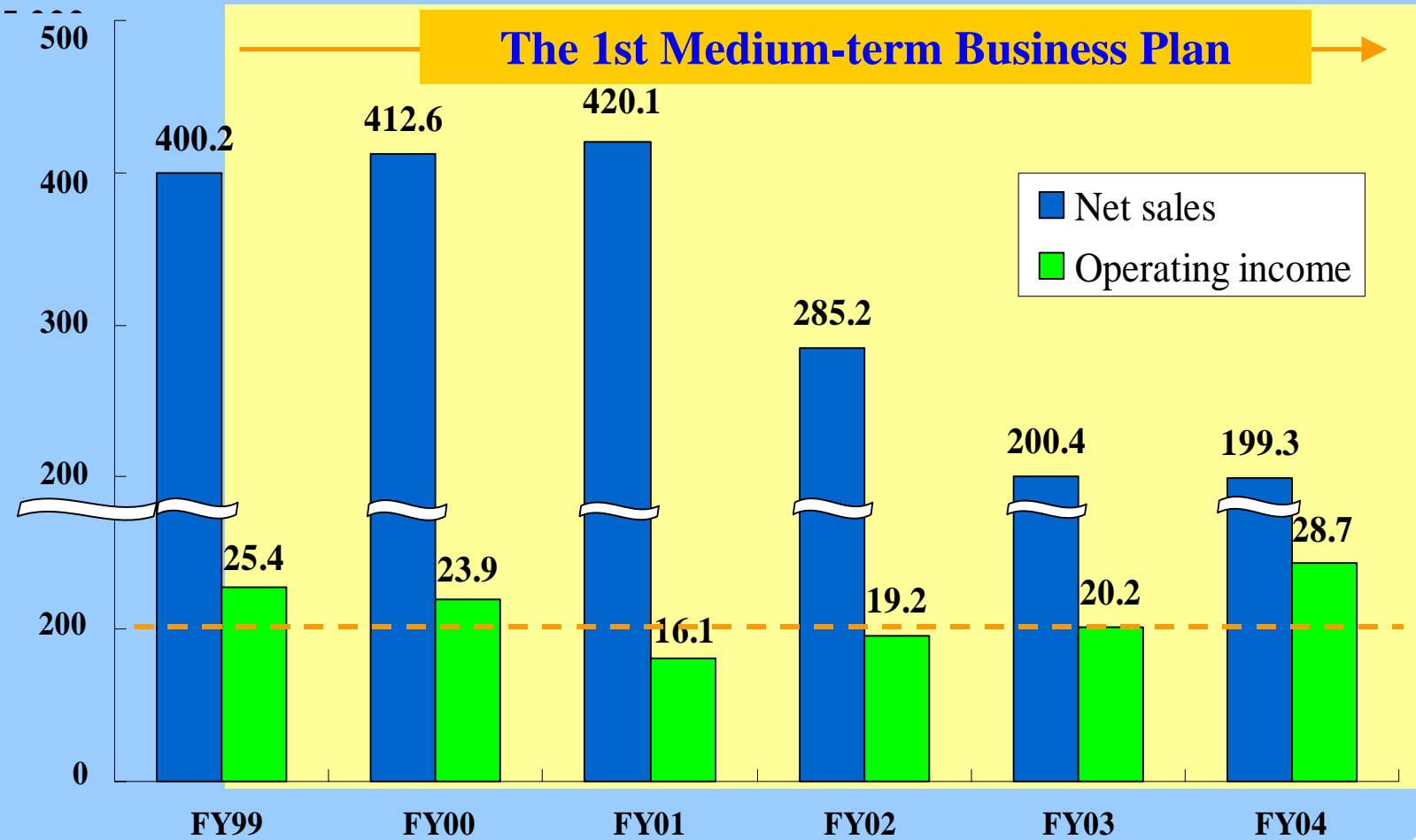
# Profit & Loss Analysis

	<u>Billions of yen</u>
<b>Revision in NHI drug prices</b>	<b>(5.0)</b>
<b>Increase in sales</b>	<b>0.7</b>
<b>Increase in royalty income</b>	<b>4.9</b>
<b>Decrease in personnel expenses</b>	<b>8.7</b>
<b>Decrease in manufacturing costs</b>	<b>1.7</b>
<b>Increase in selling and general expenses</b>	<b>(2.3)</b>
<b>Increase in R&amp;D expenses</b>	<b>(0.2)</b>
<hr/>	
<b>Total</b>	<b>8.5</b>



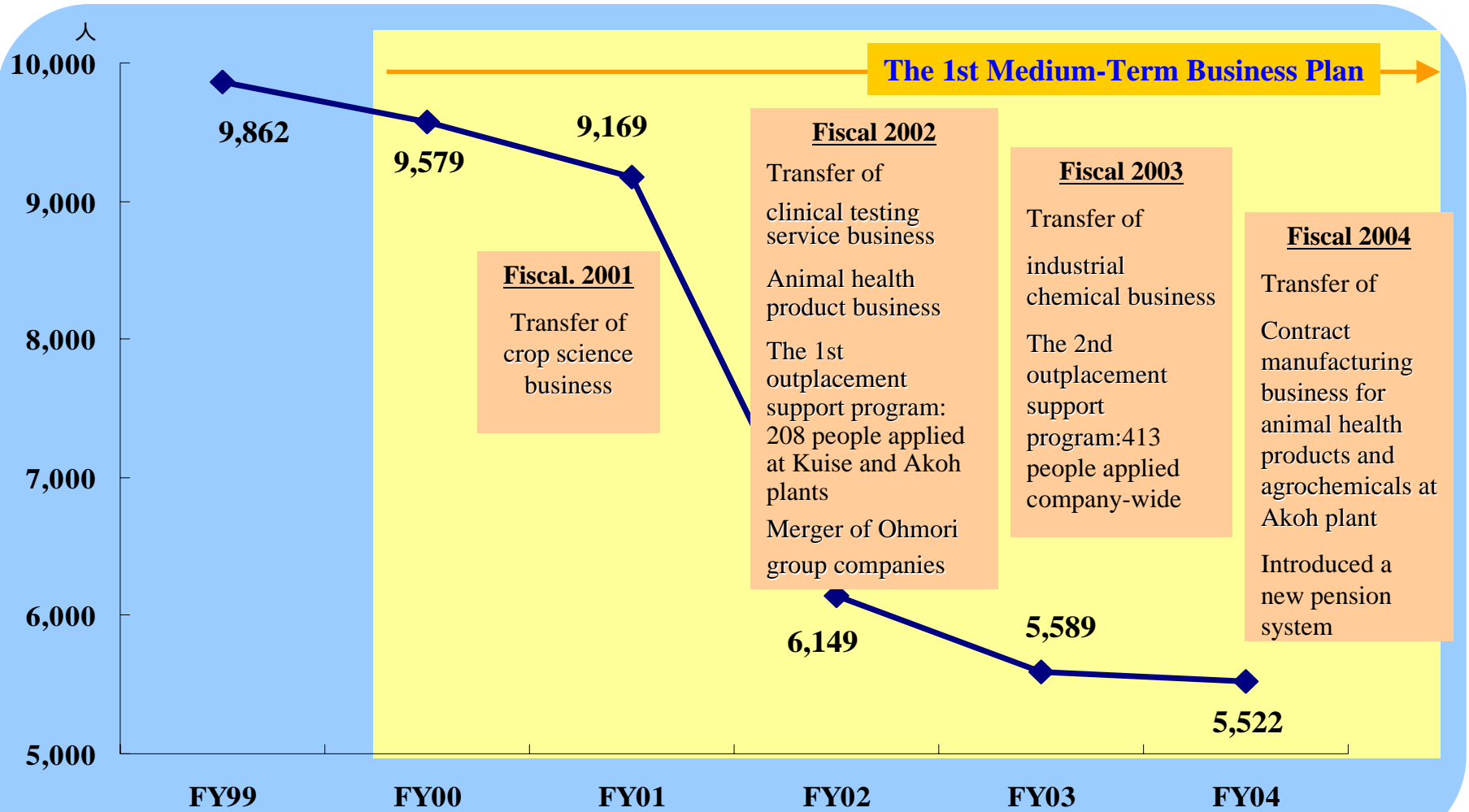
# Sales & Operating Income Trends (Consolidated)

Billions of yen





# Employees and Initiatives during the 1st Medium-term Business Plan







# Positioning of Fiscal 2005 in the 2nd Medium-term Business Plan

Concentrate on the following in the first year of the 2nd medium-term business plan

- **Research & Development**

Solid progress in 3 target research areas

( Infectious Diseases, Pain, Metabolic Diseases )

- **Sales**

Strengthen medical representative (MR) organization to maximize the value of each product in targeted therapeutic categories

- **Nurture new products**
- **Expand market share of existing products**
- **Execute post marketing surveillance study of Crestor®**



# Consolidated and Non-consolidated Forecast

	<u>Billions of yen</u>		
<b>&lt; Consolidated &gt;</b>	<b>FY05 Forecast</b>	<b>FY04 Results</b>	<b>% Change</b>
<b>Sales</b>	<b>206.0</b>	<b>199.3</b>	<b>3.3</b>
<b>Operating income</b>	<b>30.0</b>	<b>28.7</b>	<b>4.4</b>
<b>Ordinary income</b>	<b>28.5</b>	<b>27.8</b>	<b>2.5</b>
<b>Net income</b>	<b>18.0</b>	<b>18.9</b>	<b>(5.0)</b>
<b>&lt; Non-consolidated &gt;</b>			
<b>Sales</b>	<b>187.0</b>	<b>180.7</b>	<b>3.5</b>
<b>Operating income</b>	<b>26.5</b>	<b>24.5</b>	<b>7.8</b>
<b>Ordinary income</b>	<b>27.0</b>	<b>25.4</b>	<b>5.9</b>
<b>Net income</b>	<b>17.5</b>	<b>17.7</b>	<b>(1.6)</b>



# Sales by Segment (Consolidated)

Billions of yen	FY05 Forecast	FY04 Results	Increase (Decrease)	% Change
<b>Ethical drugs</b>	<b>171.5</b>	<b>168.0</b>	<b>3.5</b>	<b>2.1</b>
Flomox	34.0	33.2	0.8	2.4
Flumarin	16.0	17.0	(1.0)	(5.9)
Vancomycin	15.5	16.1	(0.6)	(3.7)
Imunace	10.7	10.4	0.3	2.9
Claritin	11.0	8.9	2.1	23.6
MS contin	4.5	5.6	(1.1)	(19.6)
Oxycontin	5.0	2.9	2.1	72.4
Crestor	0.2	0.0	0.2	-
Dripenem	1.0	0.0	1.0	-
Moxifloxacin	1.0	0.0	1.0	-
<b>OTC products</b>	<b>6.8</b>	<b>6.3</b>	<b>0.5</b>	<b>7.9</b>
<b>Diagnostics</b>	<b>3.0</b>	<b>3.5</b>	<b>(0.5)</b>	<b>(14.3)</b>
<b>Royalty income</b>	<b>10.0</b>	<b>6.1</b>	<b>3.9</b>	<b>63.9</b>
Crestor	8.5	4.8	3.7	77.1
<b>Capsule business</b>	<b>11.8</b>	<b>11.8</b>	<b>0.0</b>	<b>0.0</b>
<b>Real estate/Logistics services etc.</b>	<b>2.9</b>	<b>3.3</b>	<b>(0.4)</b>	<b>(12.1)</b>
<b>Total</b>	<b>206.0</b>	<b>199.3</b>	<b>6.7</b>	<b>3.4</b>

\* Sales of ethical drugs are shown on a non-consolidated basis.



# Cost of Sales, SG&A and Operating Income

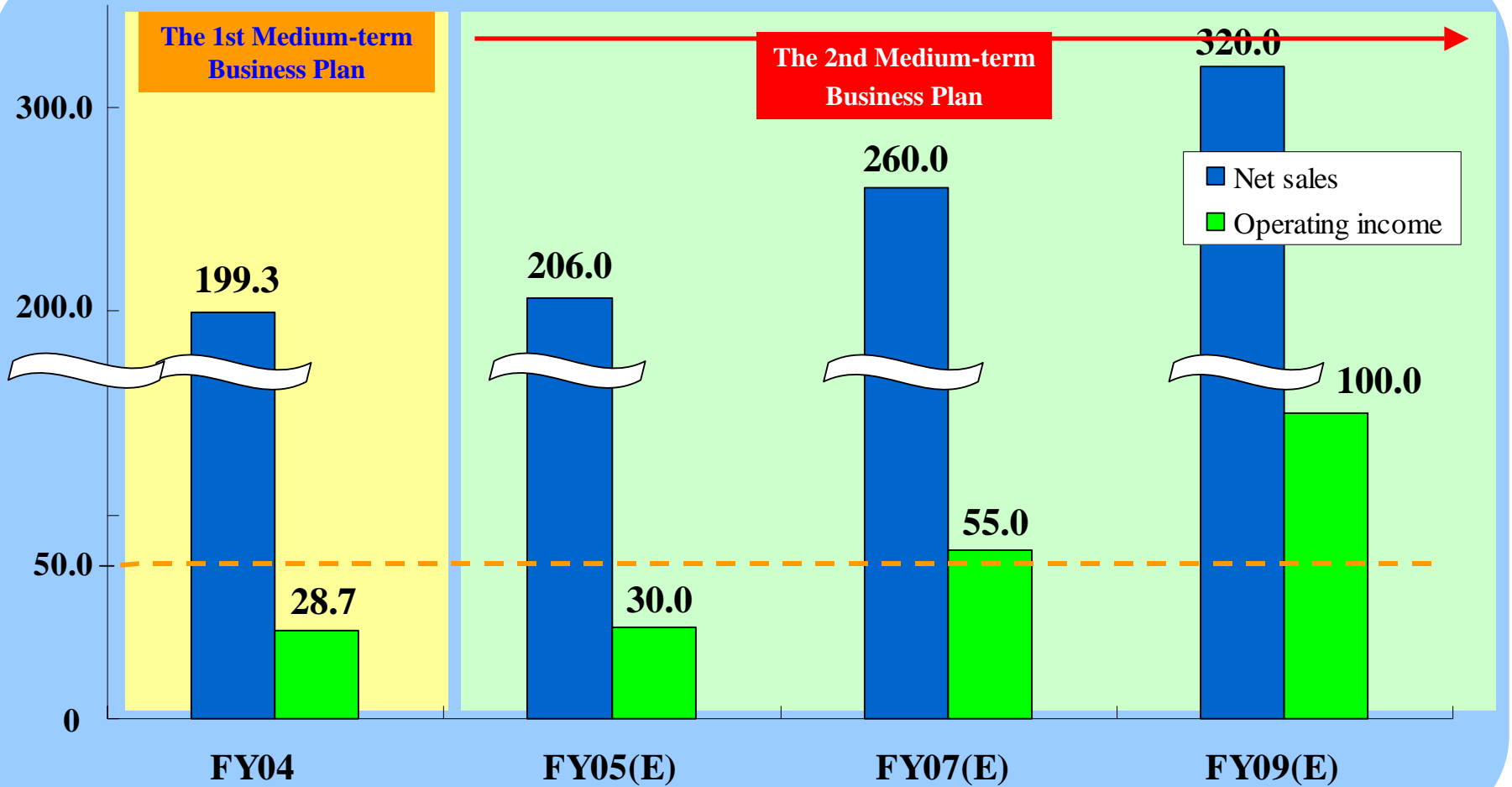
	Billions of yen			
	FY05 Forecast	FY04 Results	% Change	Increase (Decrease)
Sales	206.0	199.3	3.3	6.7
[Royalty]	[10.0]	[6.1]	63.8	[3.9]
	35.7	37.2		
	[37.5]	[38.3]		
Costs of sales	73.5	74.0	(0.8)	(0.5)
	49.8	48.4		
SG&A	102.5	96.5	6.1	6.0
Sales & General research &	68.5	67.1	2.0	1.4
Development	34.0	29.4	15.6	4.6
	14.6	14.4		
Operating income	30.0	28.7	4.4	1.3

Note: figures in parenthesis show percentage of cost of goods against sales excluding royalty



# Sales & Operating Income Trends (Forecast)

Billions of yen



(E):Estimate



# Research & Development Update (1)

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## Milestones for Fiscal 2005

**Focus drug discovery research and strategic development on  
3 selected R&D areas**

- **April 2005: Organizational changes completed at Discovery Research laboratories**
- **July 2005 : Organization changes scheduled for Strategic Development**
- **In-house R&D review committees (TA conference), in which marketing, production development and research participates, were established for the 3 selected R&D areas. R&D organization is structured to comply with the TA committees.**



## Research & Development Update (2)

### Infectious Diseases

- **S-4661 ( Doripenem )**

**Domestic : Passed drug review committee. Approval is expected in July 2005**

**Overseas: J&J announced it will acquire Peninsula Pharmaceuticals Inc.**

**Maximize the product potential based on the framework built to date**

- **Moxifloxacin**

**Preparing for product launch during fiscal 2005**

- **S-013420**

**Phase II clinical studies will begin in latter half of 2005**

- **HIV Integrase Inhibitor ( at JV with GSK)**

**Candidate compound has been selected. FTIH scheduled to begin in fiscal 2005.**



## Research & Development Update (3)

### Metabolic Diseases

- Crestor® (domestic)

**Give full support to post marketing surveillance program in preparation for IVUS testing.**

**Study group will be organized after May 2005**

- Irbesartan

**Negotiations with the authorities covering additional data are now in the final stage.**

- LY248686 (Duloxetine)

**Consulted with the authorities about clinical studies for diabetic peripheral neuropathic pain.**

**Scheduled to initiate phase II studies in autumn 2005.**





## Research & Development Update (4)

### Pain

- **Oxycodone immediate release formulation**

**Regulatory review is progressing smoothly.**

**Continuously work to obtain approval within fiscal 2005**

- **Additional indication for Oxycontin for non-cancer pain**

**Scheduled to consult with authorities in the first half of fiscal 2005**

**Clinical study is scheduled this year.**

- **Exclusive alliance agreement in the pain treatment discovery area**

**Expect to complete negotiation of agreement in the first half of fiscal 2005**



# Marketing: Nurture New Products

**Further enhance Shionogi's presence by increasing antibiotic market share.**

## **Fiscal 2005**

- **New Products: Establish speedy sales growth in Doripenem and Moxifloxacin.**
- **Promote information activities to propose treatment options according to each patient's disease status by enhancing product line-up.**
- **Promote multiple antibiotic products simultaneously at acute care medical facilities.**
  - **Injectable products: Flumarin®, Broact®, Doripenem, Vancomycin**
  - **Oral dosage form: Promote information activities for Moxifloxacin with the theme of of 'respiratory quinolone.'**

**With Flomox and Moxifloxacin, Shionogi covers both upper and lower respiratory infectious diseases are covered.**



# Marketing: Pain

**Increase information activities centered on total relief of cancer pain.**

**The 2nd half of fiscal 2004**

- **Set the target of 100% adoption by hospitals for OxyContin®**
- **Adoption rate: University hospitals 98%, Cancer centers: 100%, General hospitals with more than 300 beds: 92%**

**Fiscal 2005**

- **Achieve No. 1 combined market share for OxyContin® and MS Contin®.**
- **Promote information activities for proper use of both products according to the severity of individual patient's pain.**
- **Start information activities to eliminate pain totally at the earliest opportunity with the immediate release formulation.**
- **Organizational programs: Promote understanding of WHO system and the features of OxyContin® by holding small seminars.**



# Marketing: Claritin®

## The 2nd half of fiscal 2004

- Claritin® Reditab® induced more hospitals and clinics to adopt Claritin®.
- Hospitals and Clinics that Adopted Claritin®

1st Half : 19,343      2nd Half: 31,105

## Fiscal 2005

- Obtain 10% market share for the 2nd generation of anti-allergy products each month in the 2nd half of fiscal 2005
- Continue to enhance awareness of Claritin® with Claritin® Reditab®
- Expand information activities to allergy diseases in the dermatology field along with those in internal medicine and otolaryngology
- Promote organized activities: hold small seminars in each sales territory



# Ethical Drug Safety Monitoring Program Background

**AstraZeneca and Shionogi's stance is that patient safety is the highest priority**

## International Programs

**Final agreement on Ethical Drug Safety Surveillance Plan**

## Regulatory Programs

**Revision of the Pharmaceutical Affairs Law**

**Safety measures designed for projected conditions**



**Confirming the safety of use by Japanese is the highest priority. We will comply with the ICH E2E Guidelines for Japan, North America and Europe in planning and implementing the first drug safety surveillance program in Japan**



# Goals of Safety Surveillance Program for Crestor<sup>®</sup> Tablets

**We will focus on the next task of clarifying the Crestor<sup>®</sup> safety profile for Japanese.**

Identified task: Effect on muscles and liver

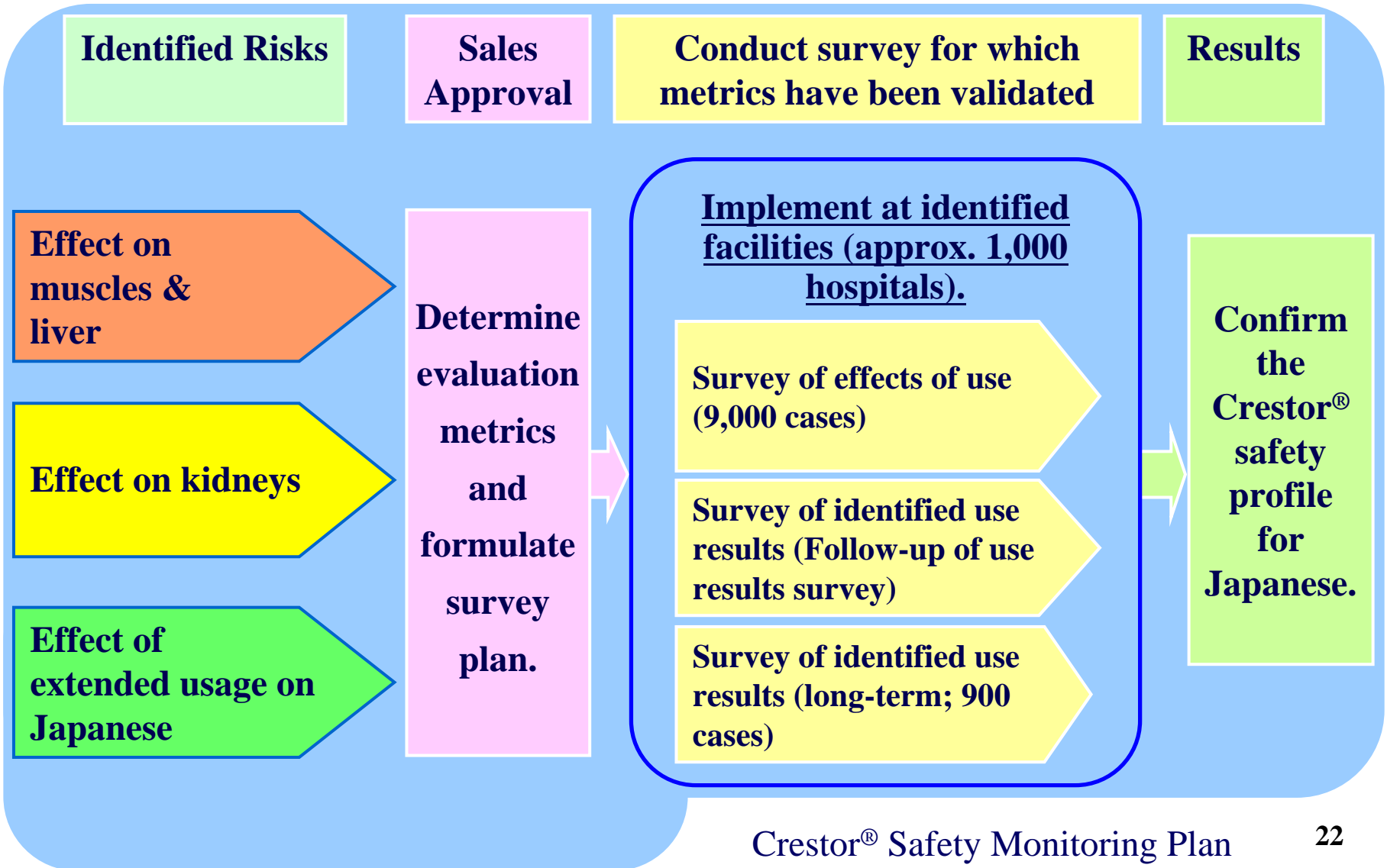
Potential task: Effect on kidneys

Insufficient information: Includes data on the effect of extended usage on Japanese

- **Quickly discover safety indications for the above and rapidly implement measures to secure safety.**



# Post Manufacturing and Sales Survey Program for Crestor<sup>®</sup> Tablets





# Collecting and Providing Safety Information

## Promoting Appropriate Use

- Request and confirm compliance with initial dosage (2.5mg)
- Request periodic clinical testing (muscles, liver, kidneys)

## Collecting Safety Information

- MRs will be in charge of drug information. They will visit medical institutions once a week to rapidly collect data on adverse reactions to Crestor<sup>®</sup> that are discovered.
- Medical specialists from Shionogi will visit medical institutions as needed and will collect high-quality technical data.

## Providing Safety Information

- Shionogi and AstraZeneca MRs will provide information to medical professionals.
- Shionogi and AstraZeneca will provide information on Crestor<sup>®</sup> via their websites.





## For further information, contact:

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