

**FUJIREBIO INC.**

August 28, 2003

# ***Fiscal Year 2003 Interim Report***

***~ Performance Review and Future Strategy ~***



**FUJIREBIO INC.**

# Consolidated Results of Profit Performance

(Millions of yen)

	2000 Interim	2003 Interim	Y/Y	2002 Annual
<b>Net sales</b>	<b>12,209</b>	<b>14,153</b>	<b>15.9%</b>	<b>26,529</b>
<b>Operating income</b>	<b>2,069</b>	<b>3,114</b>	<b>50.5%</b>	<b>4,445</b>
<b>Ordinary income</b>	<b>2,278</b>	<b>3,453</b>	<b>51.6%</b>	<b>4,727</b>
<b>Net income</b>	<b>1,585</b>	<b>2,047</b>	<b>29.2%</b>	<b>2,894</b>
<b>Equity in earnings of associated companies</b>	<b>371</b>	<b>307</b>	<b>(17.2)%</b>	<b>474</b>

**Consolidated subsidiaries:**

**TFB Inc. (Japan), Fujirebio America Inc. (USA),  
Fujirebio Diagnostics Inc. (USA), Fujirebio Taiwan Inc. (Taiwan), and  
Rebio Gen Inc.**

**Associated companies accounted for by the equity method:**

**SRL Inc. (Japan) and JGS Inc. (Japan)**



# Results of Consolidated Companies

(Millions of yen)

Company	Fujirebio Inc.	Y/Y	TFB Inc.	Y/Y	FAI(FDI)	Y/Y	Fujirebio Taiwan, Inc.	Y/Y	Rebio Gen Inc.
Sales	11,208	19.3%	2,002	0.0%	1,863	5.9%	102	(18.5)%	487
Operating profit	2,682	50.5%	33	5.5%	326	16.4%	2.5	(20.4)%	73
Ordinary profit	2,956	66.4%	33	26.3%	252	22.6%	1.6	—	66
Net income	1,502	28.4%	10	231.3%	167	24.2%	(0.1)	—	37

**Associated companies accounted for by the equity method:**

	Equity ratio	Equity in earnings of associated companies
SRL Inc.	33.4%	330 million yen
JGS Inc.	23.05%	(23 million yen)



# Consolidated Sales by Product Segments

(Millions of yen)

	2000 Interim	2003 Interim	Y/Y	2002 Annual
<b>CL-EIA based</b>	4,090	4,632	13.3%	9,004
<b>Agglutination based</b>	4,585	4,242	(7.5)%	9,404
<b>ESPLINE series</b>	221	1,286	481.9%	1,147
<b>NAT products</b>	124	434	250.3%	332
<b>RIA &amp; others</b>	3,089	3,435	11.2%	6,442
<b>Royalty</b>	98	123	25.5%	200
<b>TOTAL</b>	<b>12,209</b>	<b>14,153</b>	<b>15.9%</b>	<b>26,529</b>

**\* FY2003 Interim Sales of ESPLINE Influenza A&B: 1.06 billion yen**

\* CL-EIA: Chemiluminescent Enzyme Immunoassay

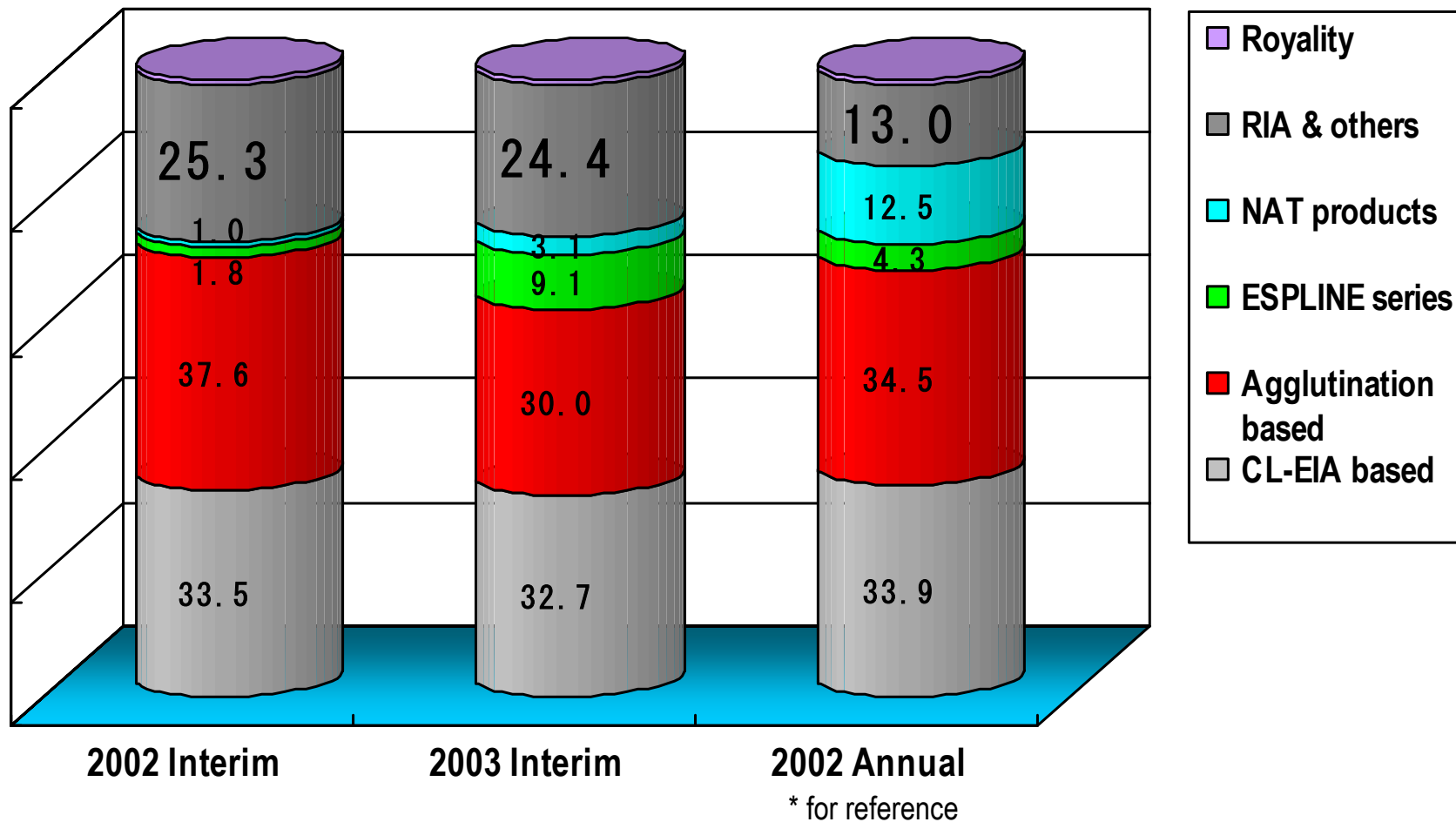
\* "Agglutination based" includes hemagglutination(HA) and Passive(Particle) Agglutination.

\* NAT: Nucleic Acid Amplification Test

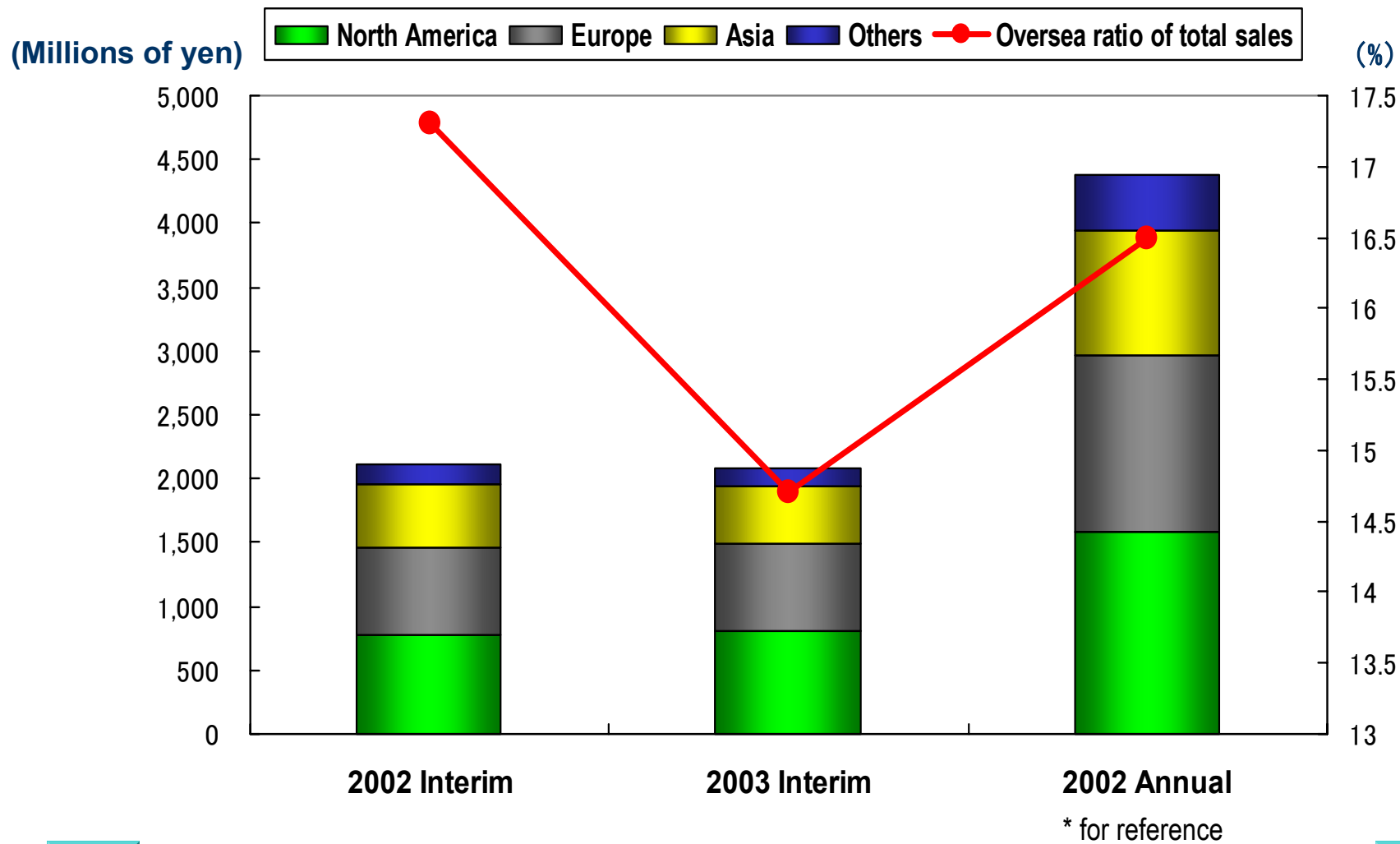


# Sales by Product Segments

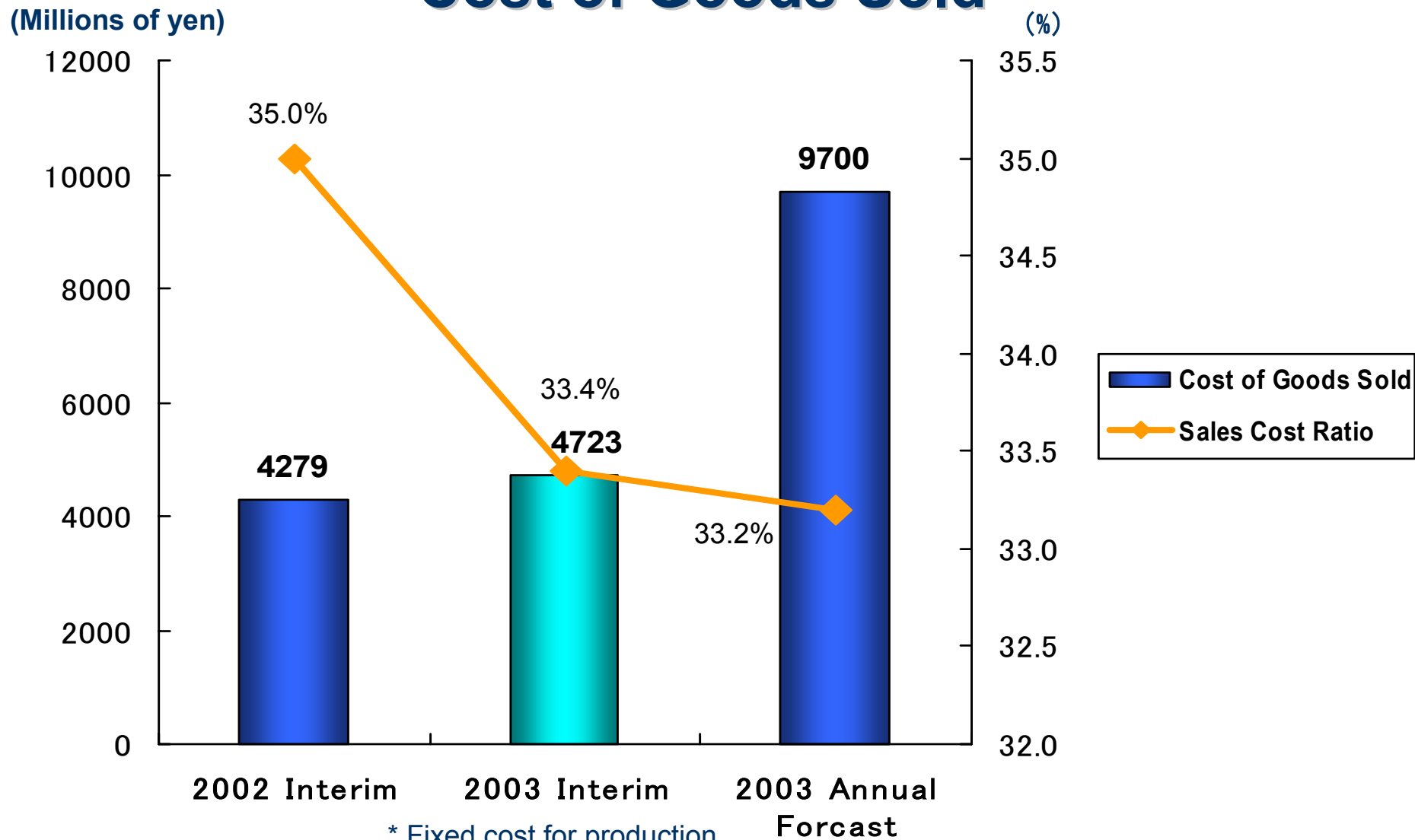
(Ratio of Sales: %)



# Sales by Oversea Areas



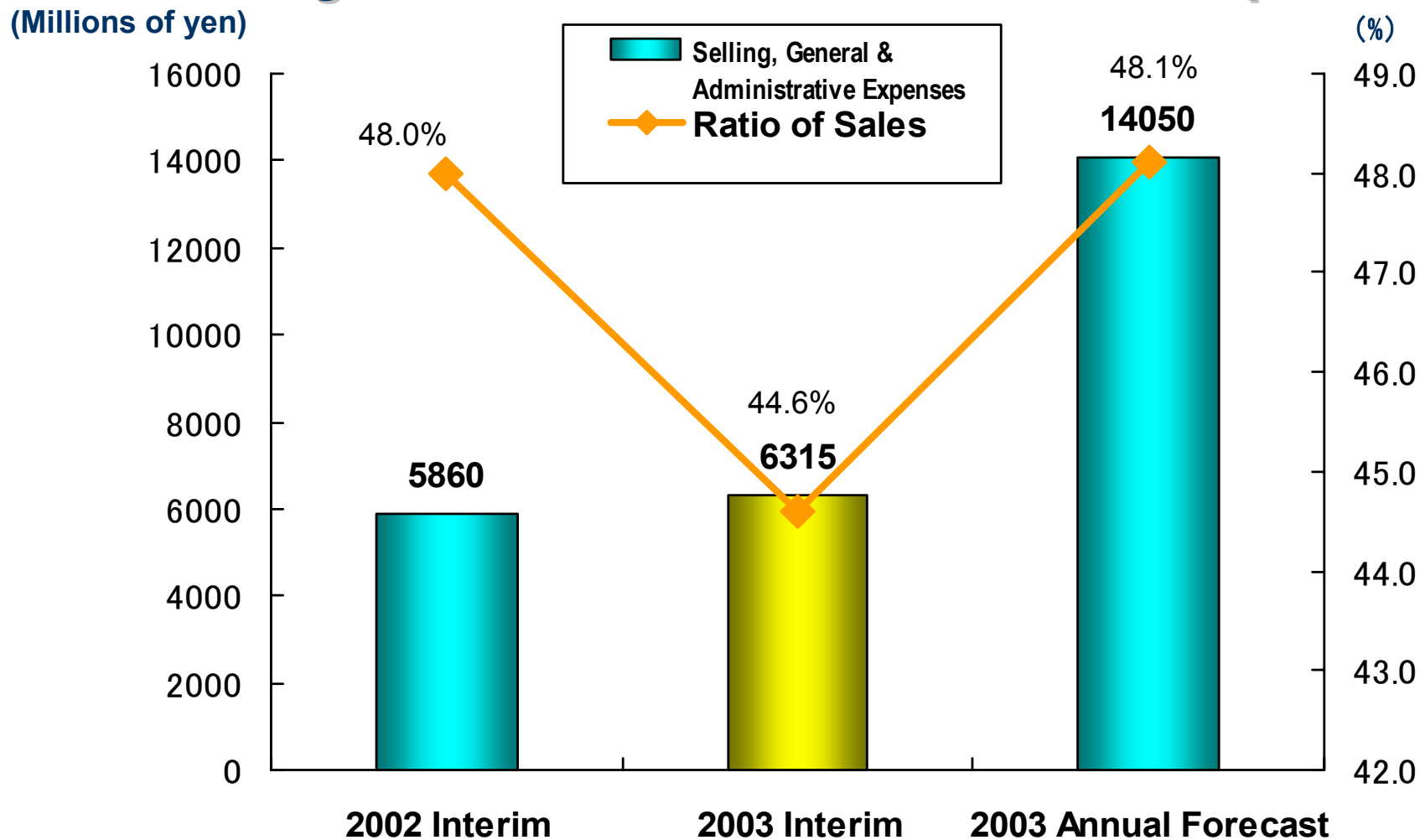
# Cost of Goods Sold



\* Fixed cost for production successfully reduced.



# Selling, General and Administrative Expenses

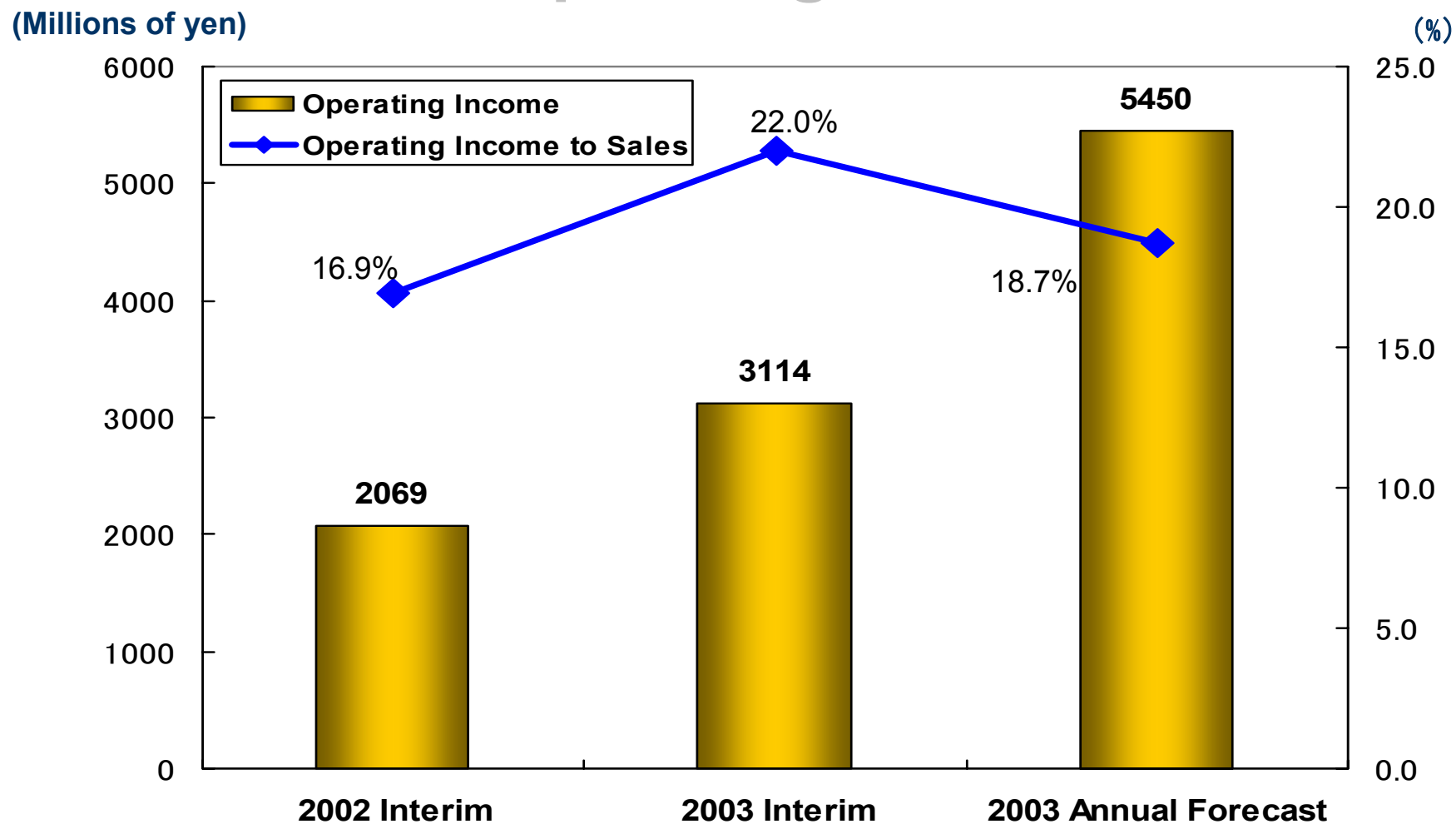


\* Sales royalty: 207 million yen

\* Consolidation adjustments account: 115 million yen



# Operating Income

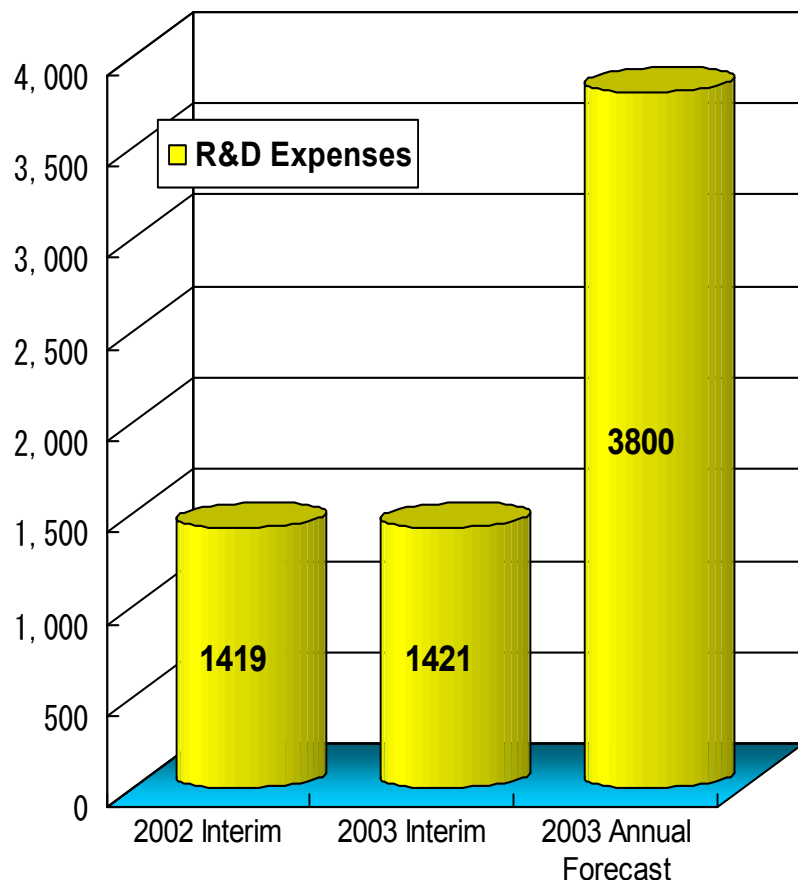


\* Goal of operating income to sales: 20%.

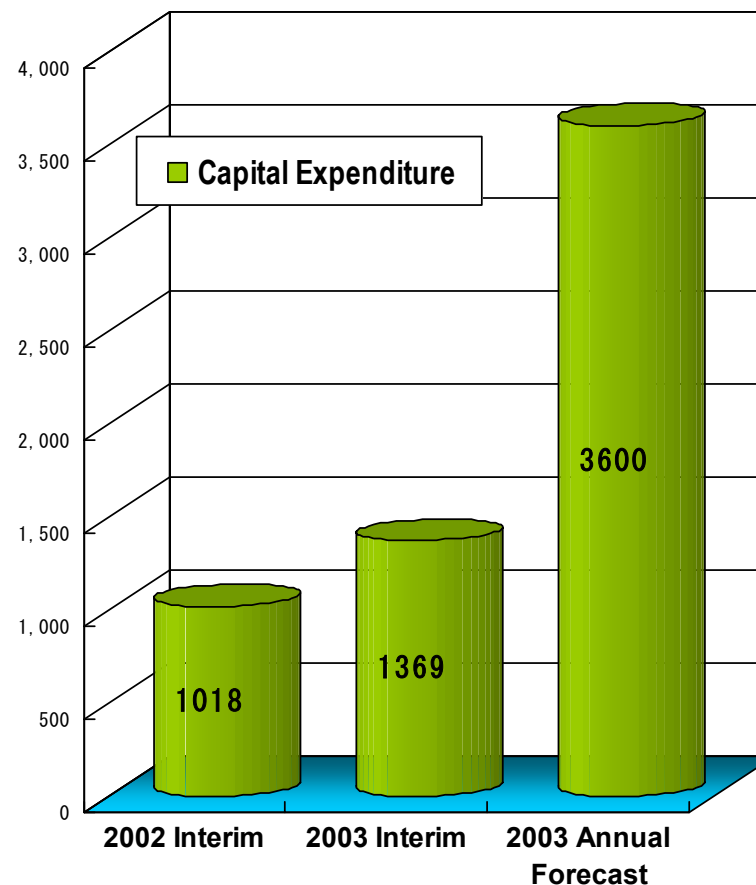


# Research and Development Expenses & Capital Expenditure

(Millions of yen)



\* Increase in R&D expenses for LUMIPULSE *Presto* for the second half of FY2003



\* Increase in Capital Expenditure for increase in productivity of ESPLINE Influenza A&B for the second half of FY 2003



# Consolidated Statement of Operations

(Millions of yen)

	2002 Interim	Ratio of net sales (%)	2003 Interim	Ratio of net sales (%)	2002 Annual	Ratio of net sales (%)
Net sales	12,209	100.0	14,153	100.0	26,529	100.0
Cost of goods sold	4,279	35.0	4,723	33.4	9,176	34.6
Gross profit	7,930	65.0	9,430	66.6	17,352	65.4
Selling, general and administrative expenses	5,860	48.0	6,315	44.6	12,906	48.6
Operating income	2,069	16.9	3,114	22.0	4,445	16.8
Other income	473	3.9	422	3.0	718	2.7
Other expense	264	2.2	83	0.6	436	1.7
Ordinary Profit	2,278	18.7	3,453	24.4	4,727	17.8
Extraordinary gain	485	4.0	168	1.2	481	1.9
Extraordinary loss	309	2.5	273	1.9	420	1.6
Income before income tax and minority interests	2,454	20.1	3,348	23.7	4,788	18.1
Income tax	944	7.7	1,213	8.6	1,882	7.1
Deferred tax	(72)	(0.6)	86	0.6	14	0.1
Minority interest	(2)	(0.0)	1	0.0	(2)	(0.0)
Net income	1,585	13.0	2,047	14.5	2,894	10.9



# Consolidated Balance Sheet (Assets)

(Millions of yen)

	2002 December	Ratio of total assets (%)	2003 June	Ratio of total assets (%)	Increase /Decrease	
<b>Current assets</b>	<b>23,521</b>	<b>39.9</b>	<b>23,316</b>	<b>39.3</b>	<b>(205)</b>	
Cash and cash equivalents	7,835	13.3	9,235	15.6	1,400	
Accounts and notes receivables	9,663	16.4	8,740	14.7	(923)	← Seasonal variation (influenza)
Marketable securities	1,020	1.7	754	1.3	(266)	
Inventories	4,427	7.5	4,049	6.8	(378)	← Compression of inventories
Deferred tax assets	276	0.5	322	0.5	46	
Other assets	332	0.6	238	0.4	(94)	
Allowance for doubtful receivables	(34)	(0.1)	(23)	(0.0)	11	
<b>Fixed assets</b>	<b>35,426</b>	<b>60.1</b>	<b>36,019</b>	<b>60.7</b>	<b>593</b>	
Property, plant and equipment	8,941	15.2	9,305	15.7	364	← Capital expenditure: 1,186 million yen
Intangible assets	3,776	6.4	3,658	6.2	(118)	
Investment securities	20,198	34.3	20,765	35.0	567	
Deferred tax assets	1,705	2.9	1,562	2.6	(143)	
Other assets	846	1.4	756	1.3	(90)	
Allowance for doubtful receivables	(41)	(0.1)	(29)	(0.0)	12	
<b>Total assets</b>	<b>58,947</b>	<b>100.0</b>	<b>59,335</b>	<b>100.0</b>	<b>388</b>	



# Consolidated Balance Sheet (Liabilities)

(Millions of yen)

	2002 December	Ratio of total assets (%)	2003 June	Ratio of total assets (%)	Increase /Decrease
<b>Current liabilities</b>	8,311	14.1	7,453	12.6	(858)
Accounts and notes payables	2,051	3.5	1,892	3.2	(159)
Short-term debt	2,635	4.5	1,835	3.1	(800)
Income tax payable	1,007	1.7	1,074	1.8	67
Accrued bonus	307	0.5	264	0.4	(43)
Other current liabilities	2,310	3.9	2,386	4.0	76
<b>Long-term liabilities</b>	12,142	20.6	11,594	19.5	(548)
Convertible bonds	6,500	11.0	6,500	11.0	0
Long-term debt	1,769	3.0	1,201	2.0	(568)
Liabilities for employee's retirement benefits	3,248	5.5	3,286	5.5	38
Liability for directors' and corporate auditors' retirement benefits	139	0.2	143	0.2	4
Other long-term liabilities	485	0.8	462	0.8	(23)
<b>Total liabilities</b>	20,454	34.7	19,047	32.1	(1,407)
Minority interest	26	0.0	27	0.0	1

Repayment of debt:  
1,368million yen

Remaining debt:  
3,036million yen



# Consolidated Balance Sheet (Shareholders' Equity)

(Millions of yen)

	2002 December	Ratio of total asset (%)	2003 June	Ratio of total asset (%)	Increase /Decrease
Common stock	3962	6.7	3962	6.7	0
Additional paid-in capital	5365	9.1	5365	9.0	0
Retained earnings	29184	49.5	30950	52.2	1766
Unrealized gain (loss) on available-for-sale securities	23	0.0	80	0.1	57
Foreign currency translation adjustments	(4)	(0.0)	(28)	(0.0)	(24)
Treasury stock at cost	(65)	(0.1)	(69)	(0.1)	(4)
<b>Total shareholders' equity</b>	<b>38466</b>	<b>65.3</b>	<b>40260</b>	<b>67.9</b>	<b>1794</b>
<b>Total asset</b>	<b>58947</b>	<b>100.0</b>	<b>59335</b>	<b>100.0</b>	<b>388</b>

\*Shareholders' equity per share in June, 2003: **934.53 yen**  
(in December, 2002: **892.79 yen**)



# Consolidated Cash Flow

(Millions of yen)

	2002 Interim	2003 Interim
Cash flow from operating activities	2,767	4,516
Cash flow from investing activities	(945)	(1,642)
Free cash flow	1,822	2,874
Repayments of debt	(837)	(1,367)
Cash dividends and others	(242)	(262)
Net increase (decrease) in cash and cash equivalents	636	1,249

\* Decrease in accounts receivable: **922 million yen**

Decrease in inventories: **379 million yen**

Capital expenditure for tangible asset: **1,186 million yen**

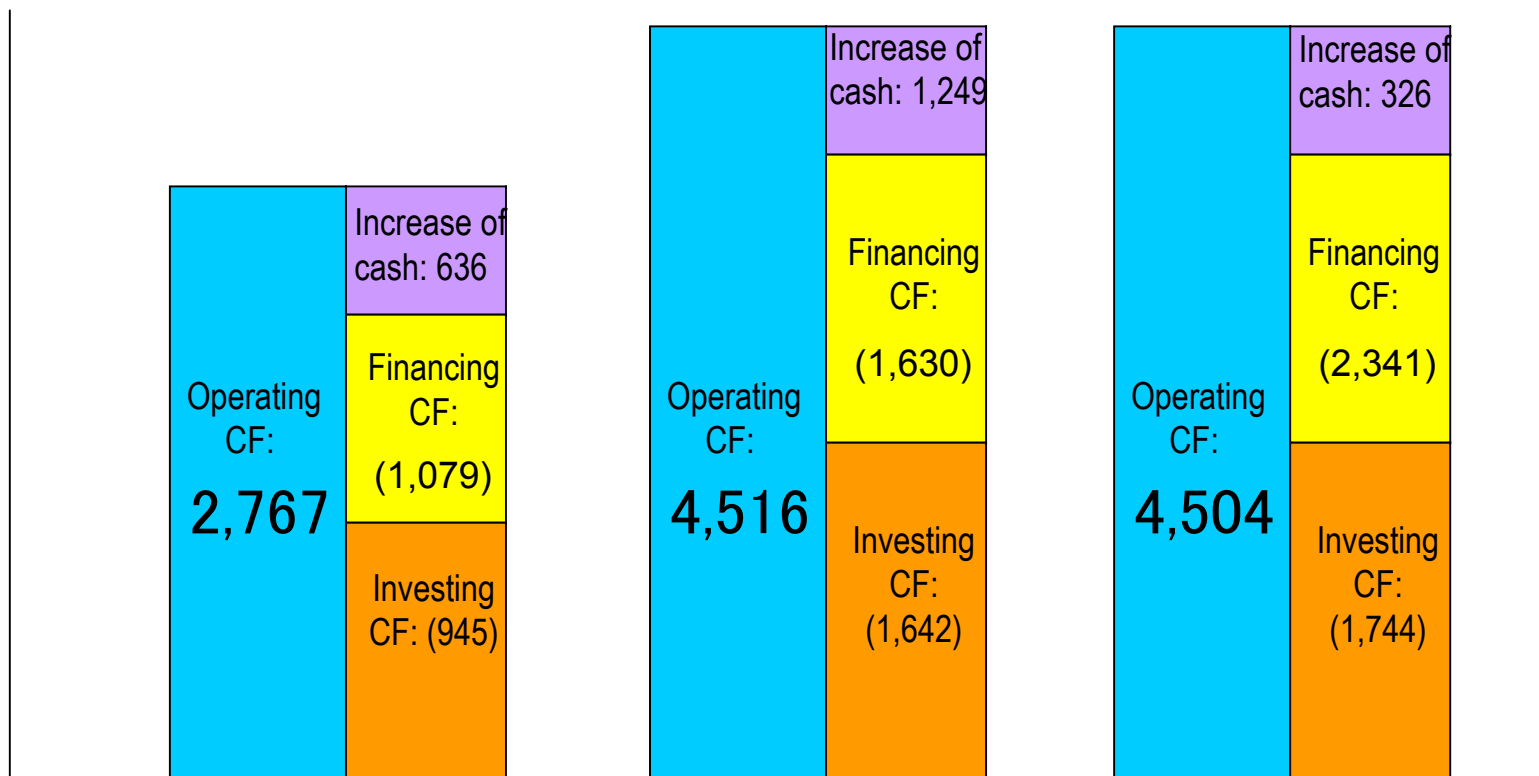
Capital expenditure for intangible asset: **253 million yen**

Repayment of debt: **1,368 million yen**



# Consolidated Cash Flow

(Millions of yen)



Cash balance: 8,676

2002 Interim

9,615

2003 Interim

8,366

2002 Annual

\* for reference



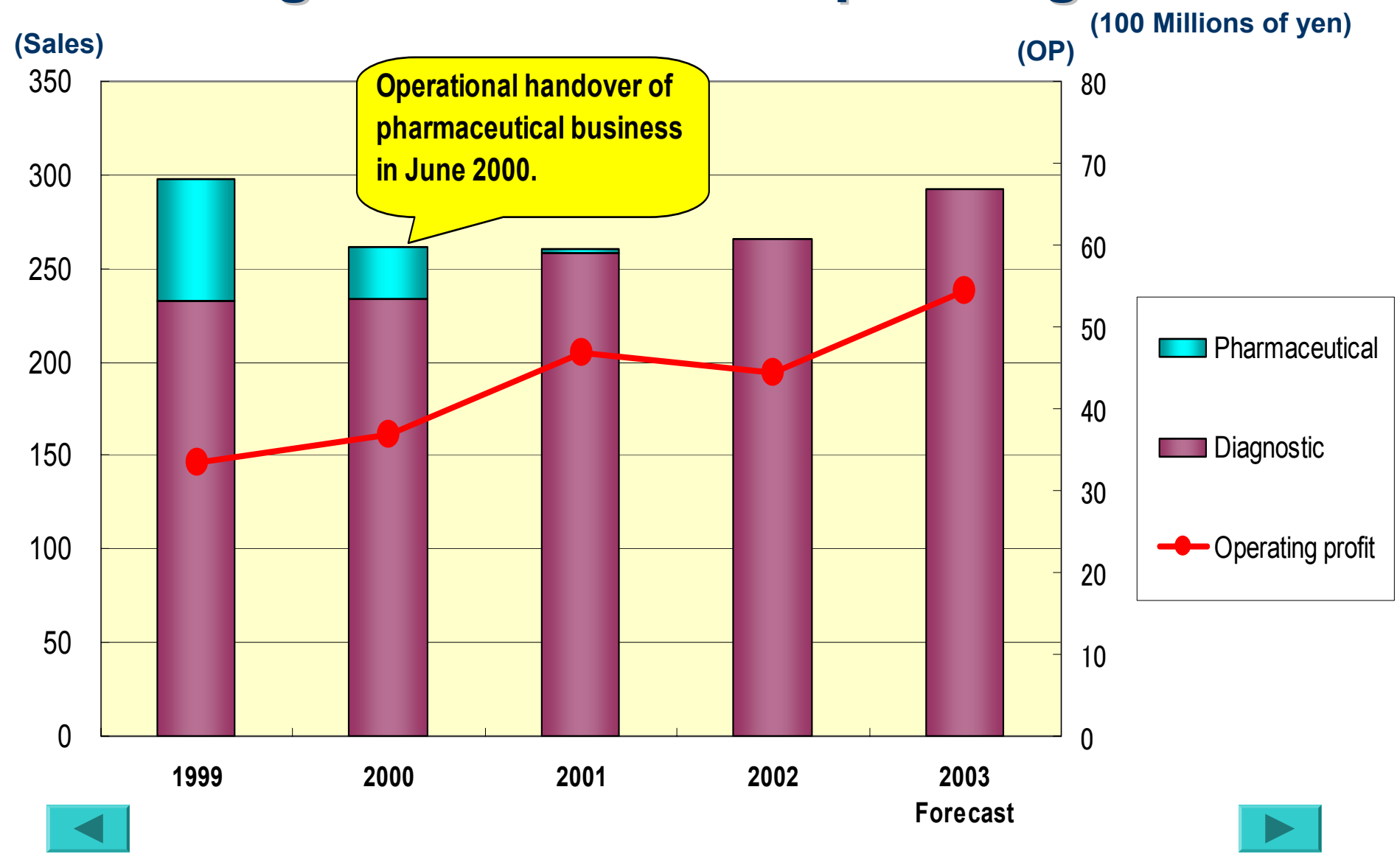
## Consolidated Annual Forecast

(Millions of yen)

	2002 Annual	2003 Annual (Forecast)	Y/Y (%)
Sales	26,529	29,200	10.1
Operating profit	4,445	5,450	22.6
Ordinary profit	4,727	5,850	23.8
Net income	2,894	3,400	17.5



# Changes in Sales and Operating Profit



# Management Policies

## Self-evolving “Value-creating Company”

Enhance our value for the society

(shareholders, customers, business partners, employees)

- Ultimate goal: “**Global Life Science Company**”
- The overwhelming NO.1 company (group) in the clinical diagnostics market in Japan
- Customer orientation (top quality, maximize “**Customers Delight**”)
- Performance-based evaluation system (principles of internal competition)
- Speedy management decision



## - OUTLINE -

- 1. ESPLINE Influenza A&B - Diagnostic Products in New Category**
- 2. Commitment to Quality Control & Quality Improvement**
- 3. Strategy for Global Business Expansion**
- 4. Sales Policy Change**
- 5. Compliance and Company Operation System**
- 6. R&D Progress**
- 7. Midterm Prospect**



# 1. EL-Influenza A&B - Diagnostic Products in New Category



	2002				2003												2004														
	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5										
Sales			* Launched																												
Production	←→				←→												←→														
Improvement	...		←→																												
Capital Expenditure											←→																				

'02/03 season: Launching as a next generation product  
 Back order volume of 2 million tests  
 → filled orders for the product by running three-shift production

'03/04 season: Upgrade the product in two phases  
 (“Improved” version and “New” version)  
 Improve in performance of the product and productivity



# 1. EL-Influenza A&B

FUJIREBIO INC

## - Product Improvement, Productivity, and Distribution Policy

### 1) Product Improvement

“Improved” version: improve in the marking line, nasal cotton-tipped swab, and squeeze tube

“New” version: use the in-house made antibody



### 2) Productivity Enhancement

Last season: sold 2 million tests in 5 months

→ **This season: estimate 3 million test in 4 months**

- Design dispensing equipment for squeeze tube and improve in productivity of cassette assembly line
- Change of procurement route for raw materials: Imported antibody from oversea

Produce antibody by FUJIREBIO (no limiting conditions for use of raw material)



### 3) Distribution Policy

- Use national distributors covering wide market area to cultivate GP\* market (Reagents MS\* unable to cover)
- Market expansion with flexibility by MS

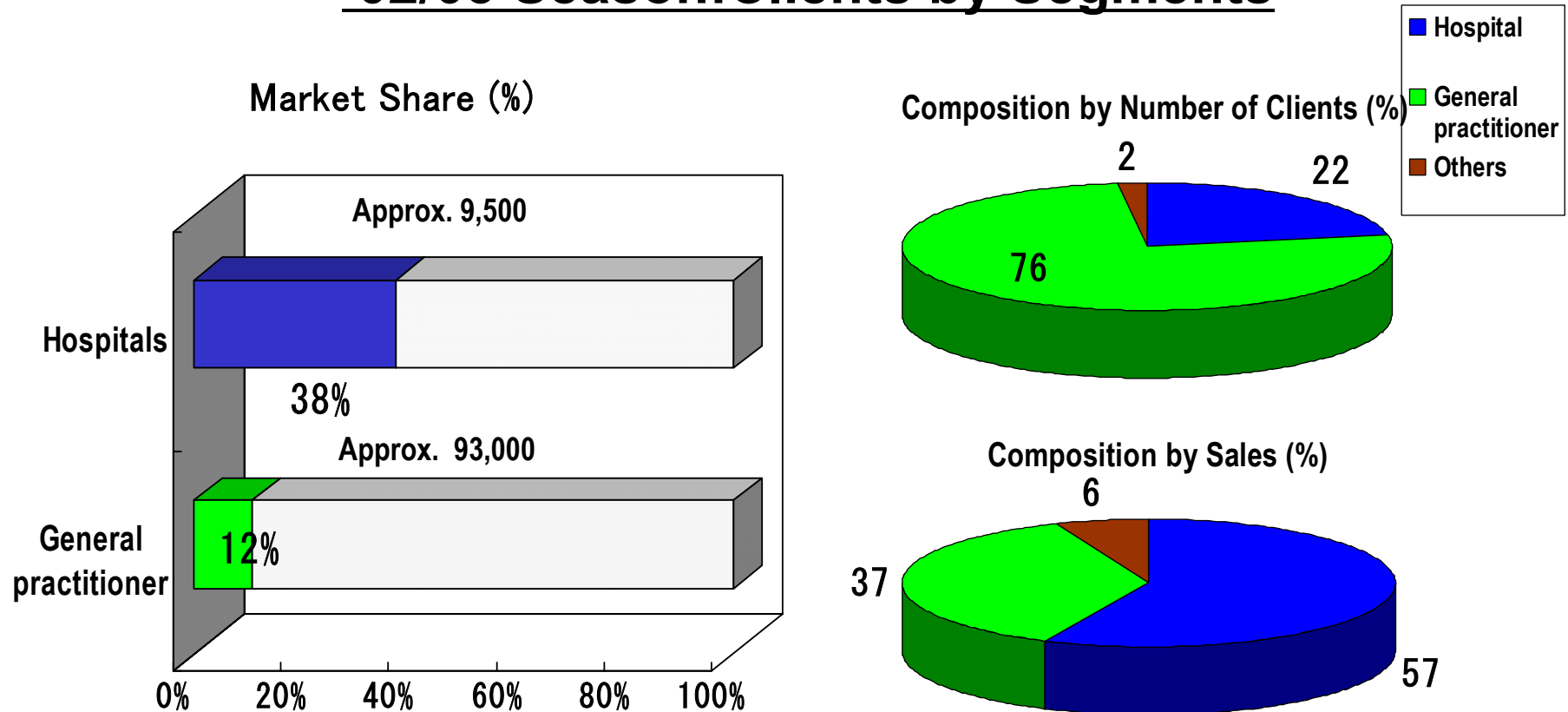


\* GP: General practitioners \* MS: Medical marketing specialists

# 1. EL-Influenza A&B - To Attract New Clients



## '02/03 Season: Clients by Segments



Market share in '02/03season : Hospital 38% General practitioner 12%

'03/04season → Many potential clients still exist in the market.

Improvement of GP market share is important. (market penetration of FUJIREBIO)



## 2. Commitment to Quality Control & Quality Improvement

FUJIREBIO INC

### Proactive product recalls for the first half of FY2003 (in Japanese market)

- Repair of LUMIPULSE f 1/10/2003
- Recall of LUMIPULSE CEA-N 2/3/2003

(reference: Fujirebio web site)

***Emphasis on quality*** →

- **First priority on initial problem solving at customers' end**
- **Enhance quality monitoring**

- *Current situation:* **Heavy work load of sales force**

- *Action:* **Drastic improvement of production and product-development process**



## 2. Commitment to Quality Control & Quality Improvement

### Complaint handling process:

- Quality control system and complaint processing system based on ISO9001/13485 (After Service Group)
- Prompt investigation/response and establishment of improvement plan
- Coordination between Sales Division and New Product Planning & Development Division

### Speedy directive of improvement:

- Directive of improvement from \*KYFR meeting (reflect complaints from customers and set up foremost task)

### Regular quality monitoring:

- Customer satisfaction survey (the 2<sup>nd</sup> survey in progress)

### Study by working group



\* KYFR Meeting: the monthly meeting chaired by the President, the name stands for our slogan “how far Fujirebio can get for our customers!?”



## 2. Commitment to Quality Control & Quality Improvement

FUJIREBIO INC

### Quality Improvement Working Group

(Interdisciplinary organization among younger generation staff from production, quality control, product development, quality system and other departments)

#### 1) Product planning:

Review of product planning process, enhancement of product data traceability, and increased use of risk analysis

#### 2) Process flow control:

Planning of production process/quality, and renewal of process flow control and monitoring system

#### 3) Quality control:

Thorough use of quality data from raw materials to products, and adaptation to multiproduct small-lot production



**Quality is the key for competitive product differentiation.**

**Need for speedy response to quality problems  
(concrete implementation plan is required.)**



### 3. Strategy for Global Business Expansion

FUJIREBIO INC

Current overseas sales:

decreasing Agglutination based diagnostic products

→ **Need for transition to LUMIPULSE system**

Planning of overseas sales of LUMIPULSE new generation system

- Completed a feasibility study for US market and concrete business planning in process
- Global Marketing Department (established on 8/1/'03)
- Exhibit LUMIPULSE *Presto* at AACC 2003 Clinical Lab Expo

→ **Start on overseas business expansion plan (utilization of FDI)**



### 3. Strategy for Global Business Expansion



#### AACC 2003 Clinical Lab Expo

July 20-24, 2003 Pennsylvania Convention Center, Philadelphia, PA

Exhibit: LUMIPULSE Presto



# 4. Sales Policy Change

## Sales policy

### 1) Distribution policy

Quotation price system: no major changes on incentive level to distributors

→ No significant negative impact on FUJIREBIO's sales

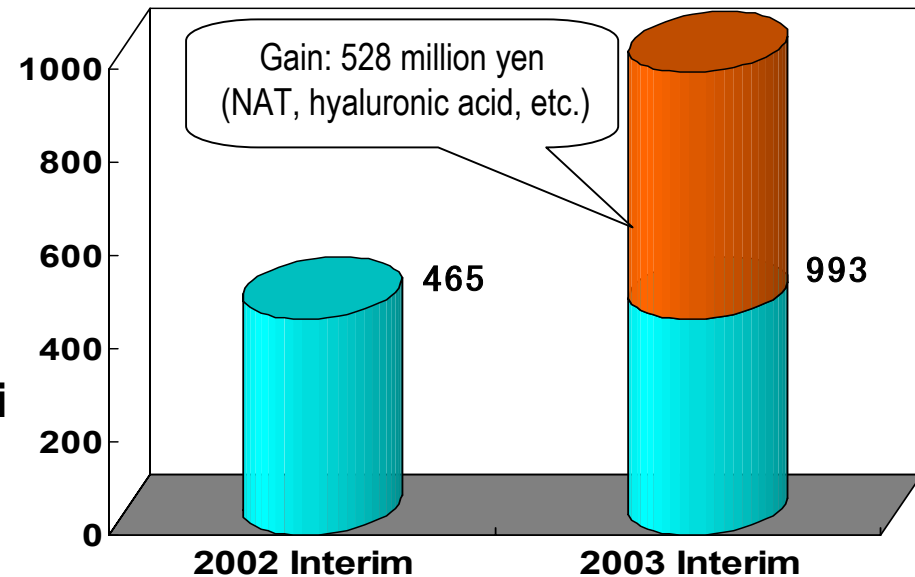
Improve distribution system for more aggressive promotion activities in future

### 2) Business with commercial laboratory

Sales amount with three major commercial lab. in 2003

- double of 2002

Contribution by acquisition of Chugai Diagnostics Science Co., Ltd. (CDS)



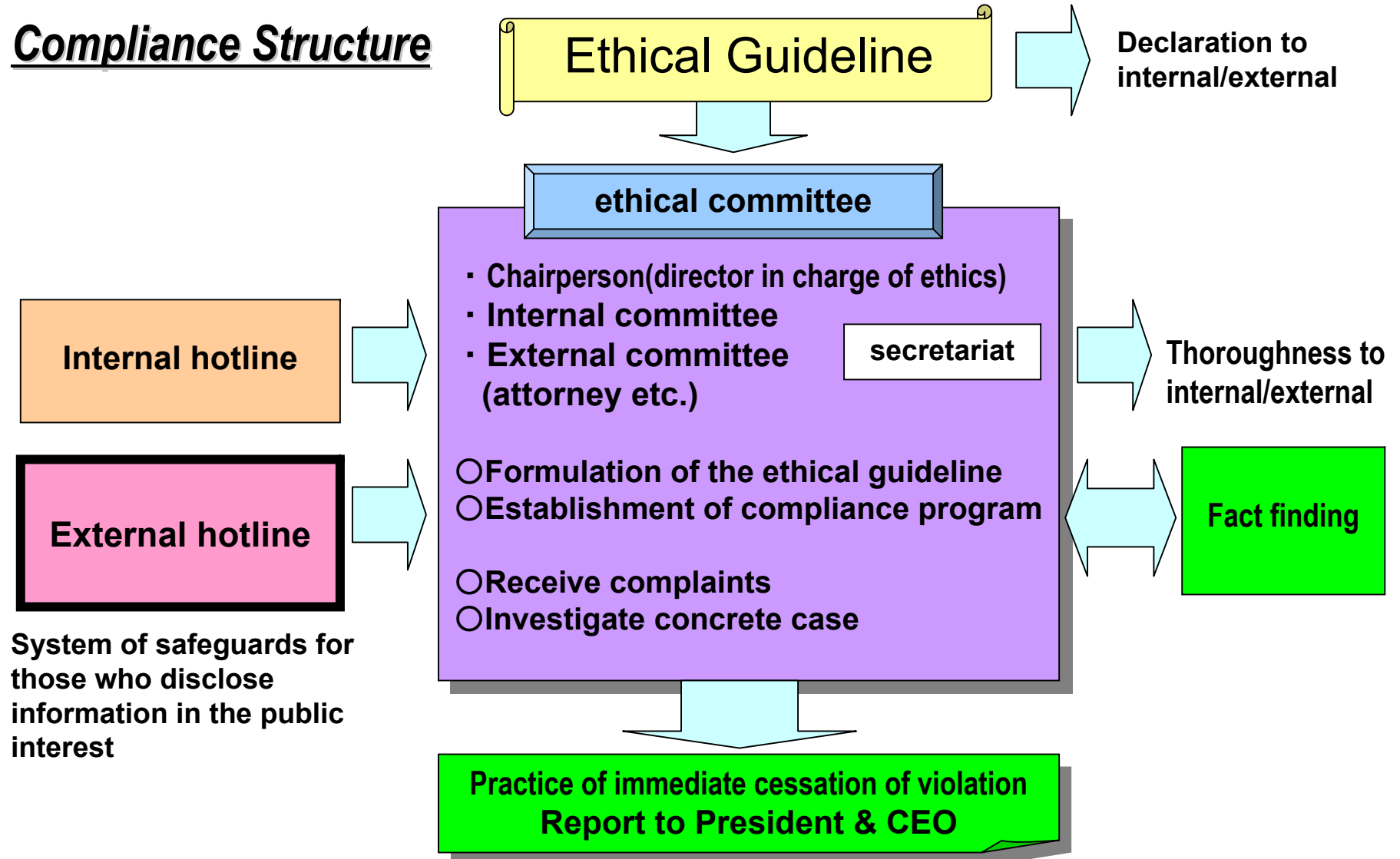
→ Increase in the product lines for commercial lab. (specific analytes lines)  
Further steps to increase such new analytes lines in future



# 5. Compliance and Company Operation System

FUJIREBIO INC

## Compliance Structure



System of safeguards for those who disclose information in the public interest

**Start in fall 2003**



## 5. Compliance and Company Operation System

### Operation system

- **Version-upgrade: ISO 9001/13485**

(ISO 9001 → 2000 version、 ISO 13485 → 2003 version)

(Scheduled to obtain first-in-Japan CE marking on List A diagnostic product)

- **Company operation system**

- (Total renewal of core and MIS computer system)**

(New HR management system is already in operation, other systems in June, 2004)

- **The 2nd Customer Satisfaction Survey**

- **Selective Educational System (Management Training Program)**

(Regular internal selective education by executives and external educational program (10 staffs to be sent))



## 6. R&D Progress

### *LUMIPULSE Presto*

*Fully automated analyzer and reagents*

**Scheduled to be  
launched in Nov. 2003**

Trust on LUMIPULSE  
brand name

**Overwhelming numbers installed  
LUMIPULSE series**

Top-class performance

- **High throughput: 240 Tests/h**
- **24 analytes available for full  
random access method**

A wide selection of reagent menu

- **Tumor maker, infectious disease,  
hormone, etc.**



### **Lumipulse *Presto***

Economical efficiency

- **Adoption of master calibration**
- **Smaller loss of diluted solution**

Smaller and efficient  
test space

- **Switch over to bottle  
typed reagent**

Environmental consciousness

- **Decrease of waste  
for disposal**



## 6. R&D Progress

### Protein Bio Chip (PBC):

- Completed introduction of production equipment
- Technological challenges for commercial production
- Sales start-up delay by half year expected  
(not including business expansion for research purpose)



→ **focus on technical development (Simultaneous Multiple Immuno Assay), which takes time to develop for business**

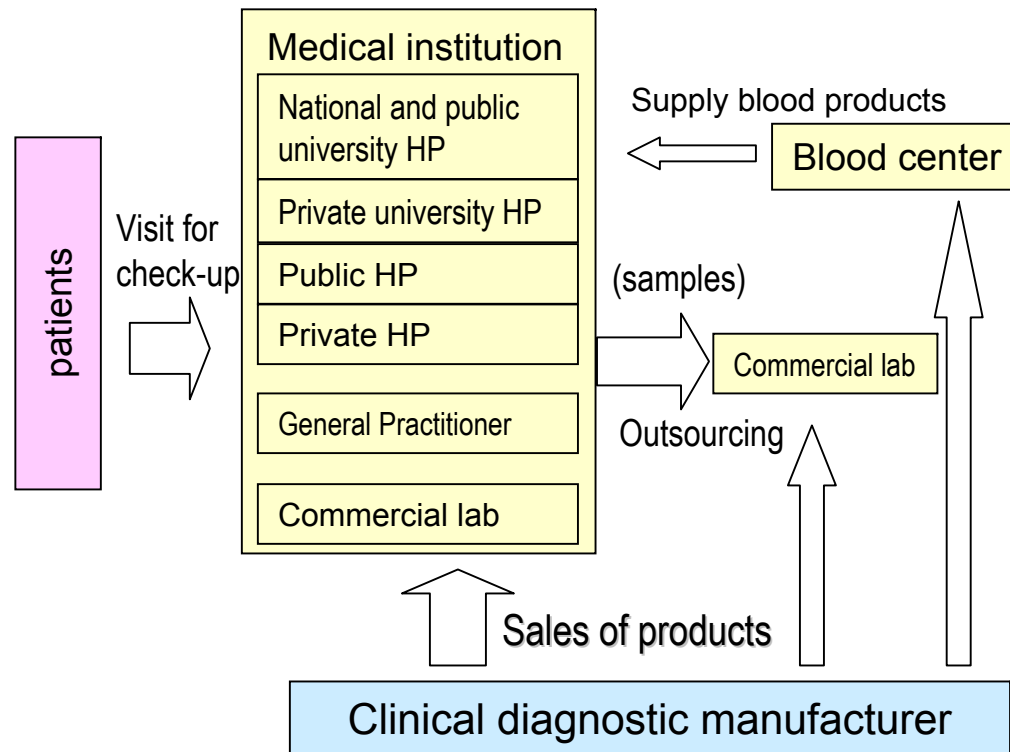
**Start from support of drug discovery and development for the present, ultimately toward to diagnostic field**

### Advanced research:

- Create future key technology for bio-based components
- 3 special teams working on each project
  - “Bioarchitecture”
  - “Bionanosensors”
  - “Bioinformatics”



# 7. Midterm Prospect ~market situation~



## Fluctuation factors of market

### <Medical institution>

- Instruction of DPC
- Incorporation of national universities
- 30% burden of medical payment under the national insurance scheme
- Lower medical treatment fees (lower NHI point)
- Pursuit of profitability

### <Commercial lab>

- Contract price decline by competition for order

### <Blood center>

- Improvement of business operation under the new legislation for blood transfusion

## Market situation

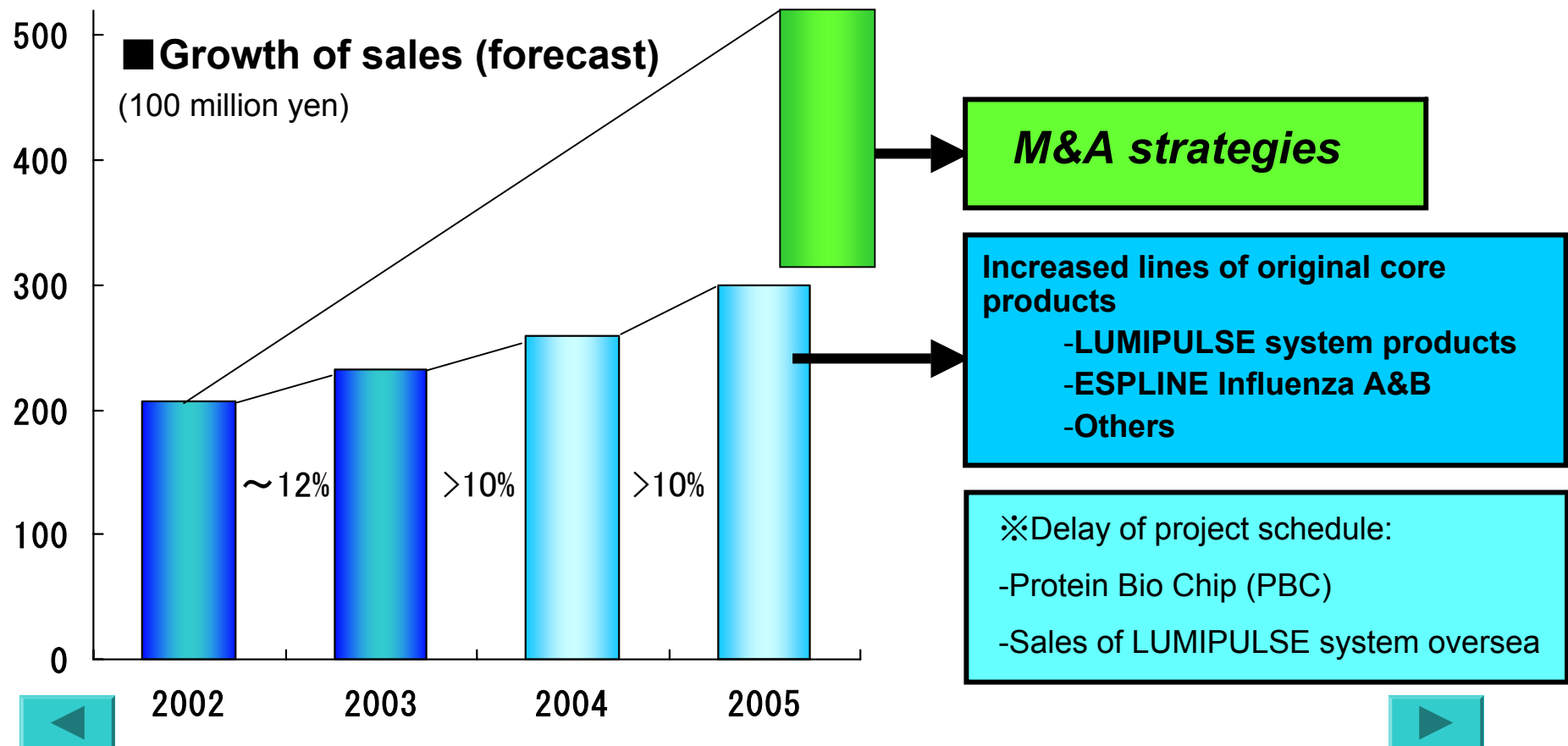
- 1) In-house clinical test → outsourcing, cost-conscious ↓
- 2) Price competition in commercial lab → cost down for medical procurement → slimmer profits margins ↓
- 3) Continuing demand for “high value and importance of laboratory test” (increasing)  
Need of transformation for laboratory test operation for higher-value analytes (ex.POCT)
- 4) **Conclusion: each company’s own business strategy/marketing management makes a difference.**



# 7. Midterm Prospect

Corporate entity with the single entity sales of 50 billion yen

- Overwhelming presence in the clinical diagnostics business in Japan
- Efficient operation (operating profit rate: 20%, ROE: 10%)



## Contact: IR & PUBLIC RELATIONS TEAM

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