

Obelisk 2019

FY2019/3 H1 Presentation

November, 2018

Nichi-Iko Pharmaceutical Co., Ltd.

President & CEO

Yuichi Tamura



Nichi-Iko Pharmaceutical Co., Ltd.

FY2019/3 H1 Overview (IFRS)

■ Operating profit and Net profit were revised upward despite NHI drug price revision offset by volume growth of domestic GE, cost reduction by Profit Management Plan, and unused SG&A.

Sales	(FY2018/3 H1 83.0B JPY) 82.3B JPY (+) GE volume growth (-) NHI drug price revision
Operating Profit	(FY2018/3 H1 2.6B JPY) 4.7B JPY (+) Profit Management Plan (+) Unused SG&A and R&D
Net Profit	(FY2018/3 H1 2.4B JPY) 4.6B JPY

FY2019/3 H1 Financial Highlights by Segment (YOY)



(Million JPY)	Japan + Others			Sagent			Consolidated		
	FY2018/3 H1	FY2019/3 H1	YOY	FY2018/3 H1	FY2019/3 H1	YOY	FY2018/3 H1	FY2019/3 H1	YOY
Sales	64,184	63,853	99.5%	18,875	18,493	98.0%	83,060	82,346	99.1%
COGS	48,088	50,009	104.0%	16,113	14,157	87.9%	64,202	64,166	99.9%
Gross Profit	16,095	13,843	86.0%	2,762	4,335	157.0%	18,858	18,179	96.4%
SG&A	8,601	8,474	98.5%	3,212	3,140	97.8%	11,813	11,615	98.3%
R&D expense	1,278	1,203	94.1%	698	711	101.9%	1,977	1,915	96.9%
Other Income	671	273	40.7%	-14	0	-	657	273	41.6%
Other Expense	54	90	167.7%	2,975	111	3.7%	3,029	202	6.7%
Operating Profit	6,834	4,348	63.6%	-4,138	372	-	2,695	4,720	175.1%

**Interim
Dividend
(planned)
15.0 JPY**

**Capital investment
2.2B JPY
(FY2018/3 H1 5.8B JPY)**

**R&D investment
5.1B JPY
(FY2018/3 H1 3.9B JPY)**

**Depreciation
4.6B JPY
(FY2018/3 H1 4.1B JPY)**

FY2019/3 H1 Financial Highlights by Segment (vs Plan)



(Million JPY)	Japan + Others			Sagent			Consolidated		
	Plan	Actual	%	Plan	Actual	%	Plan	Actual	%
Sales	65,000	63,853	98.2%	17,000	18,493	108.8%	82,000	82,346	100.4%
COGS	52,000	50,009	96.2%	13,000	14,157	108.9%	65,000	64,166	98.7%
Gross Profit	13,000	13,843	106.5%	4,000	4,335	108.4%	17,000	18,179	106.9%
Operating Profit	2,900	4,348	150.0%	100	372	372.0%	3,000	4,720	157.3%

Sales Increase/Decrease & Factor Analysis (IFRS)

(Million JPY)

FY2018/3 H1

83,060

GE



+726

LLP



-516

Others (Domestic)



-541

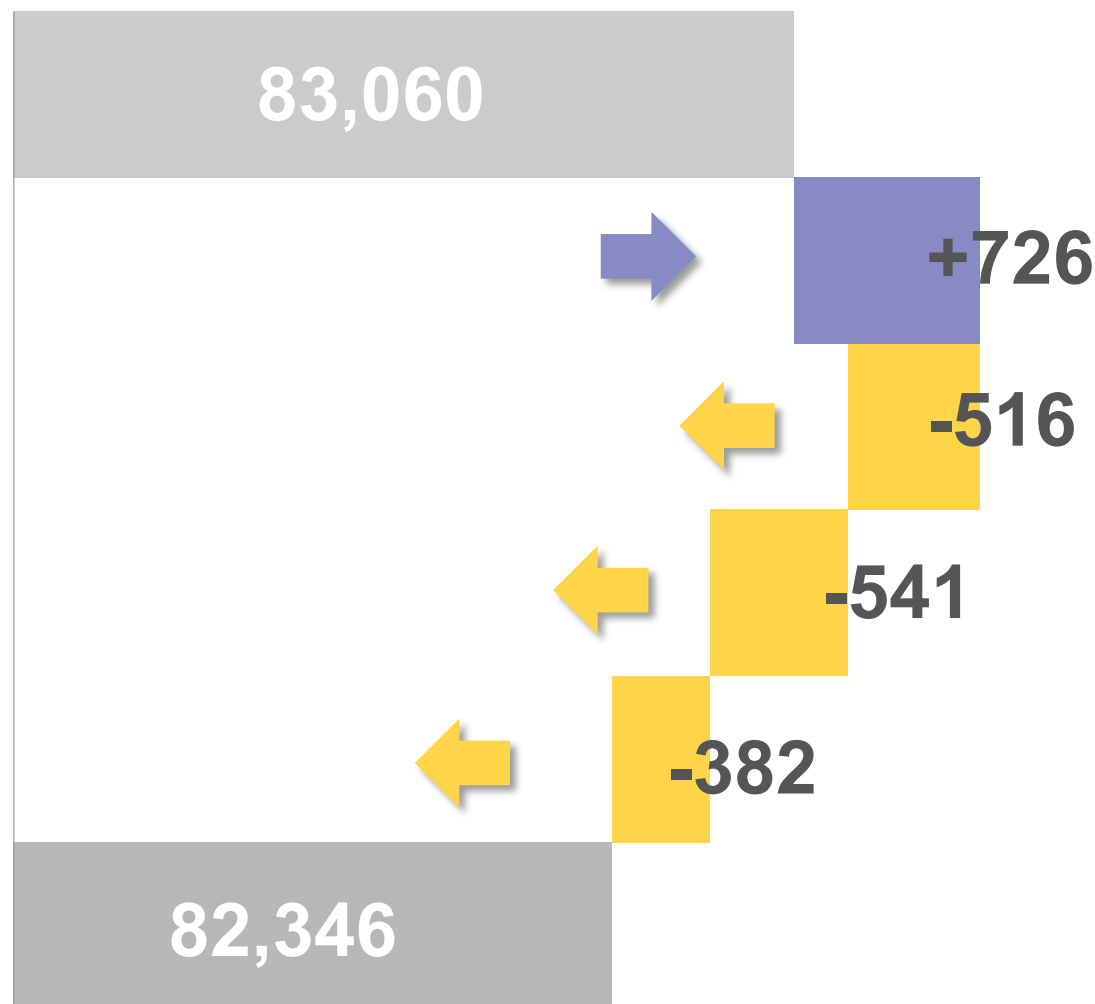
Sagent



-382

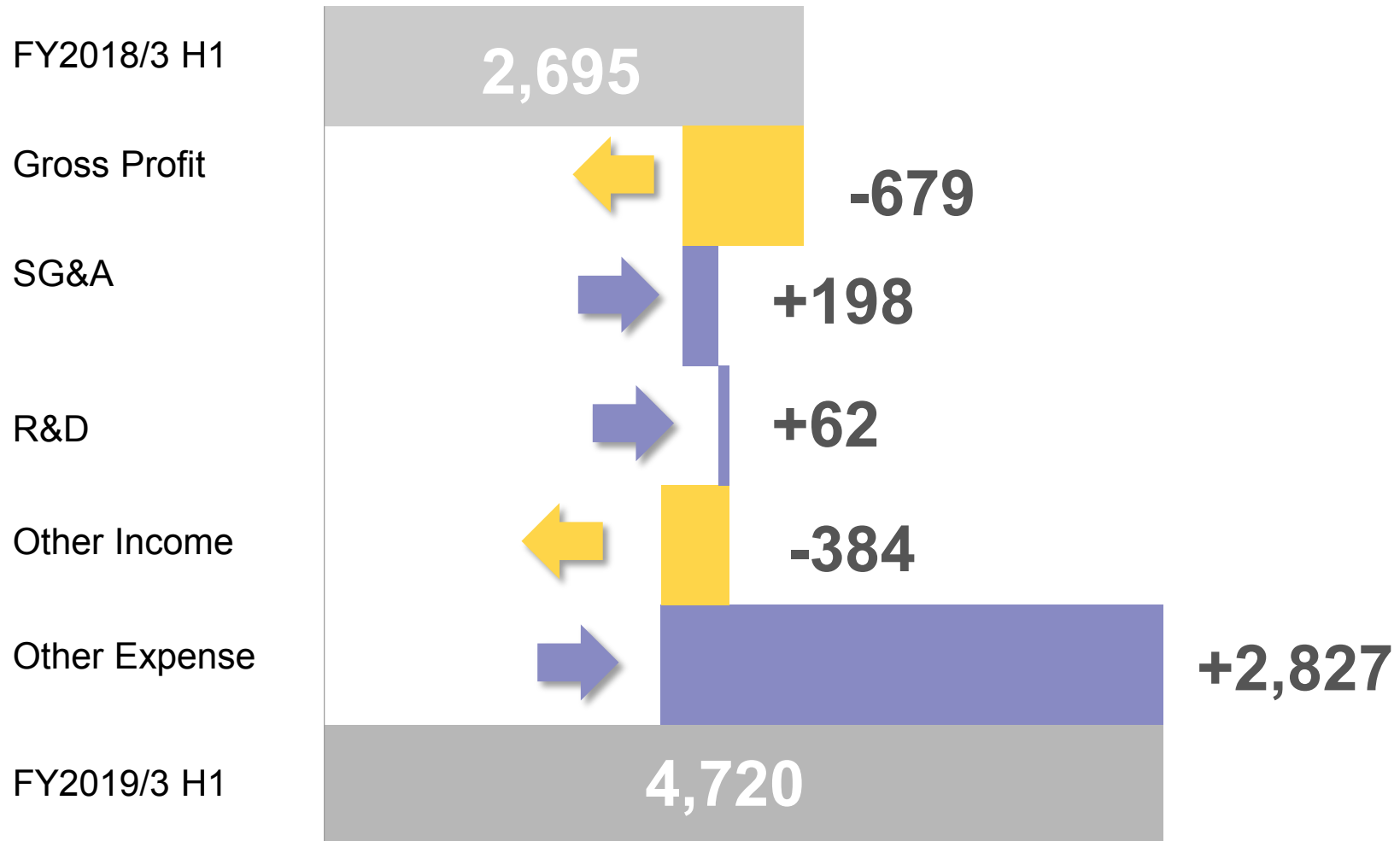
FY2019/3 H1

82,346



Operating Profit Increase/Decrease & Factor Analysis (IFRS)

(Million JPY)



Operating Profit Variance to Forecast

Variance to the forecast was 1.7 B JPY; OP actual of 4.7B JPY to OP forecast of 3.0 B JPY.

(Billion JPY)

Factors	Amount
• Reduced Variable cost by PMP etc. • Product mix • Improved supplying price	1.4
• Re-examined R&D expense due to PMI with Elmed and unused R&D expense	0.8
• Improved gross profit at Sagent	0.3
• Increased other expenses etc.	Δ0.8
Variance	1.7

Progress of Profit Management Plan

Realized 5.0B JPY cost reduction from Apr. 2017 to Sep. 2018 while planning 6.0B JPY cost reduction until Mar. 2019

Yield Rates improvement	+	+
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Disposal Reduction of unfinished goods	+
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Disposal Reduction of finished goods	-	-
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Cost Reduction of API	+	+	+
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Cost Reduction of packaging materials	+
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Achieved
5.0B JPY
cost reduction

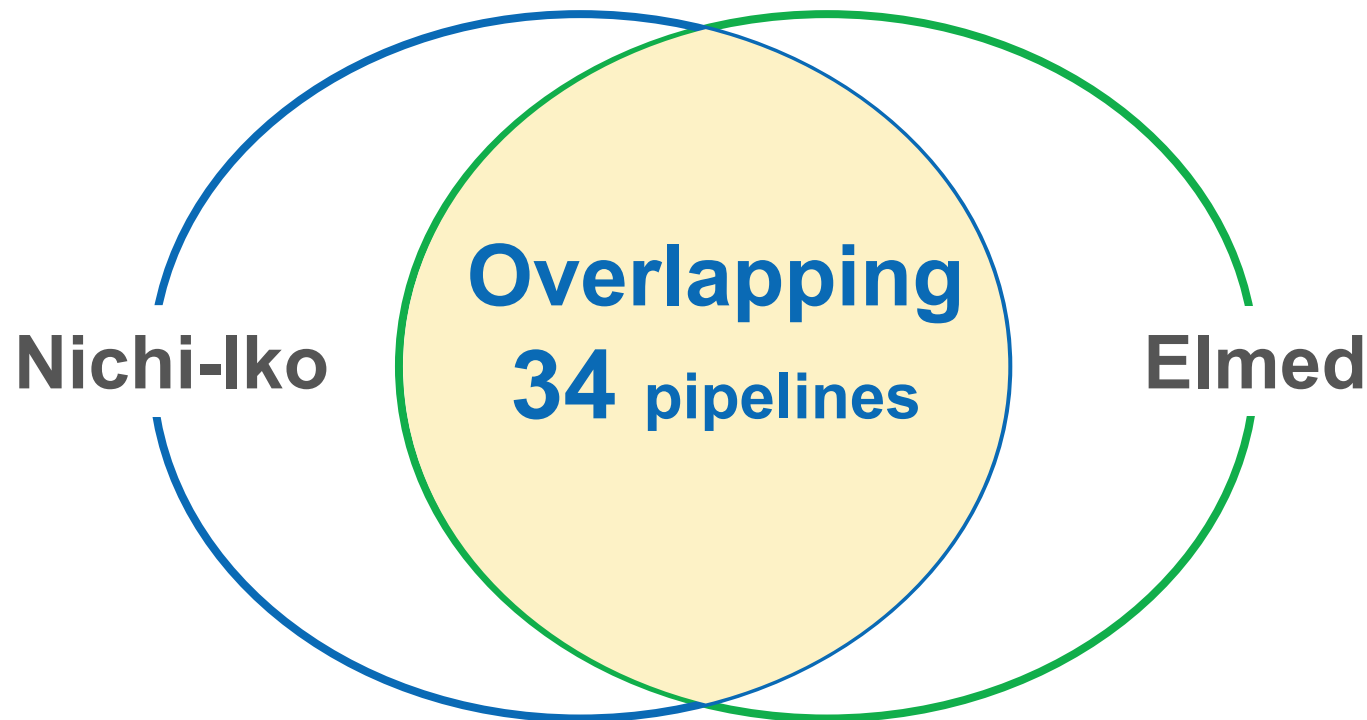
Target
6.0B JPY

PMI Progress



Product integration by COGS and formulation for **34 duplicated pipelines.**

- ✓ Cost Synergy in R&D expense
- ✓ In-house production of Elmed pipeline products by Nichi-Iko
- ✓ Increased efficiency to strengthen the development and IP team function

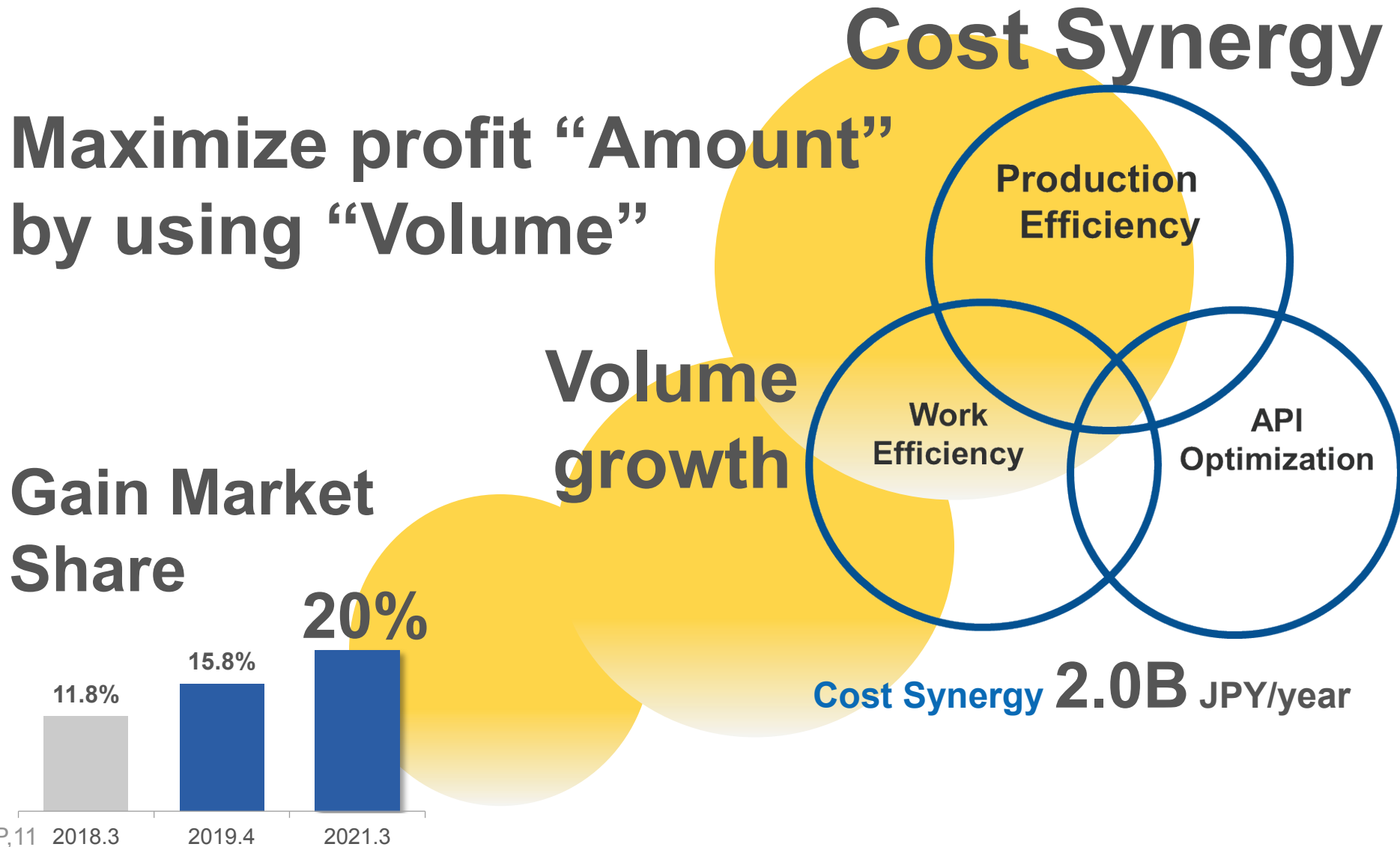


Oct. 1st, 2018

Started Co-promotion of Elmed's value added products by Nichi-Iko

No.	Product	Feature
1	Famotidine D tab.	Molded tablet
2	Enalapril M tab.	Molded tablet
3	Menilet 70% Jelly	Unique dosage form
4	Isosorbide Dinitrate tape	Superior usability
5	Docetaxel I.V. infusion	Alcohol-free fomula

In terms of co-promotion of Nichi-Iko products by Eisai, product selection has finished and planned to be commenced sequentially.



PMI④__API (Business with Eisai's India Plant)



- ✓ Procurement of superior price competitive API from Eisai
 - ✓ Utilization of Eisai's API development capability and manufacturing techniques for new products
 - ✓ Contract manufacturing at Vizag Plant in India with low costs and advanced technology
- **Evaluating candidate products**

Marketed products

scheduled to be approved from **FY2020/3 H1**

Pipeline products

evaluated in time with approval timing

CMO production

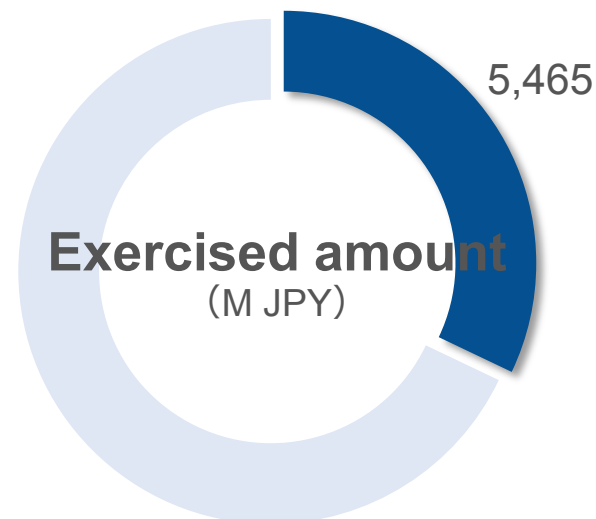
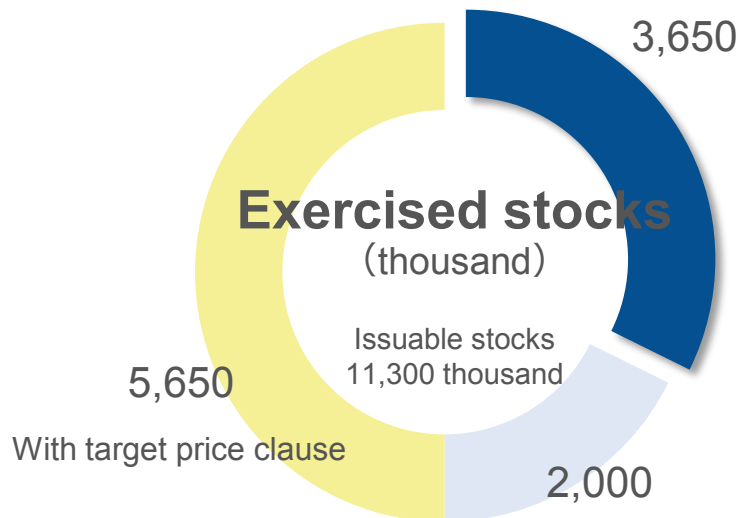
considering candidates ingredients

Planned to expand the candidates

Current status of equity financing

Financing correspond to phased acquisition of Elmed Eisai stocks
Acquired 33.4% stocks as of Oct. 1st, 2018 with 5.6B JPY

	Exercised stocks (thousand)	Exercised amount (M JPY)
Aug. 2018	1,650	2,414
Sep. 2018	1,000	1,515
Oct. 2018	1,000	1,536
total	3,650	5,465



- **US Market Conditions**
- **Biosimilars**
- **ASEAN Market conditions**

US Market Conditions & Pipeline Progress

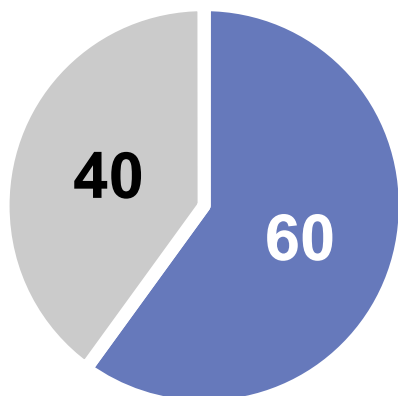
Current

ANDA approval process acceleration caused an increase in number of market players and price competition
Continued strong price pressure from GPO

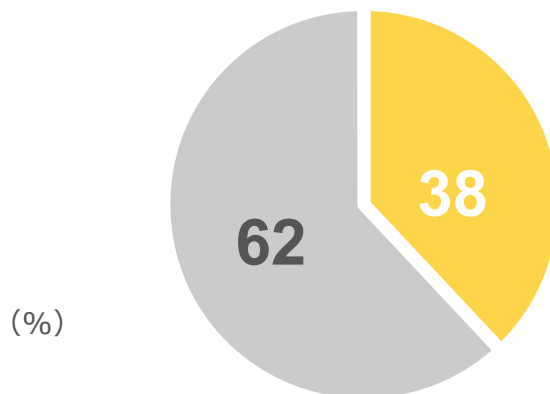
Action

Launched 8 products during first half

**Sagent
Top10 products sales**

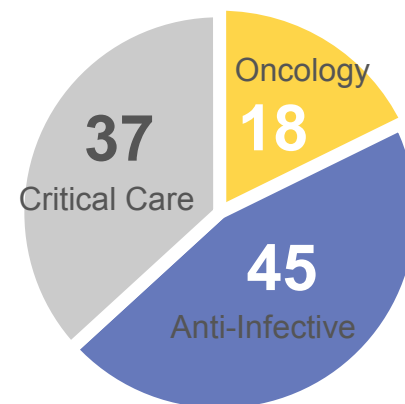


**Sagent Newly marketed
products sales※**



※Sales of products launched in FY2018/3 and FY2019/3H1.

**Sagent
Sales by areas**



	FY2018/3	FY2019/3	FY2020/3	Total
Number of launched and/or planned to launch products	13	8/12-17 Launched/planned total launch number in the FY	8-12	33-42

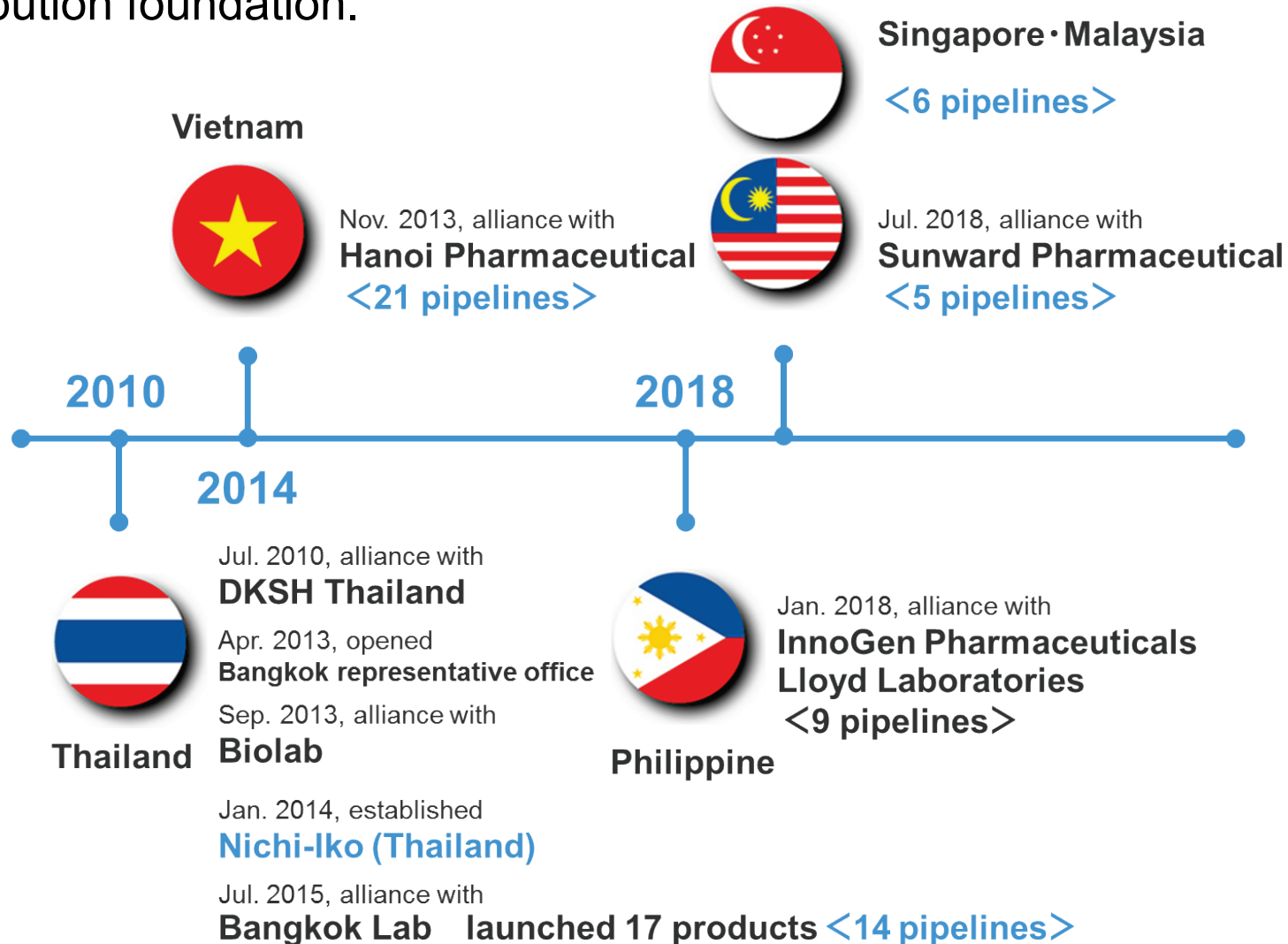
Development status of Biosimilar pipelines

- **Infliximab** Final stage of “Interchangeability” PhaseⅢ study in the US
- **Etanercept** Planning to sell “Kyowa” product and be transferred to Nichi-Iko after one year from the launch
- **Trastuzumab** Phase I study has started in the US

	Pre-clinical	Phase I	PhaseⅢ	Filing/Approval
Infliximab (Japan)	Launched (Approved in Sep. 2017)			
Infliximab (US)	Final stage of PhaseⅢ (To be filed in 2019)			
Etanercept (Japan)	Filed in Mar. 2018			
Trastuzumab (Japan,US,EU)	Started Phase I in the US			

ASEAN Market conditions

Expanded to ASEAN 5 countries. Enhancing product portfolio and marketing and distribution foundation.



2019/3 Revised full year outlook (IFRS)

Revised financial outlook based on the favorable H1 result.

(Million JPY)	Previous Forecast		Revised Forecast		Variance (Consolidated) Δ
	Consolidated	Sagent	Consolidated	Sagent	
Net Sales	172,000	35,000	170,000	36,000	Δ2,000
COGS	136,000	26,500	132,500	27,500	3,500
Gross Profit	36,000	8,500	37,500	8,500	+1,500
Operating Profit	8,000	200	9,500	500	+1,500
Net Profit	5,000	150	7,000	350	+2,000

Annual Dividend
30 JPY / Share
(Planned)

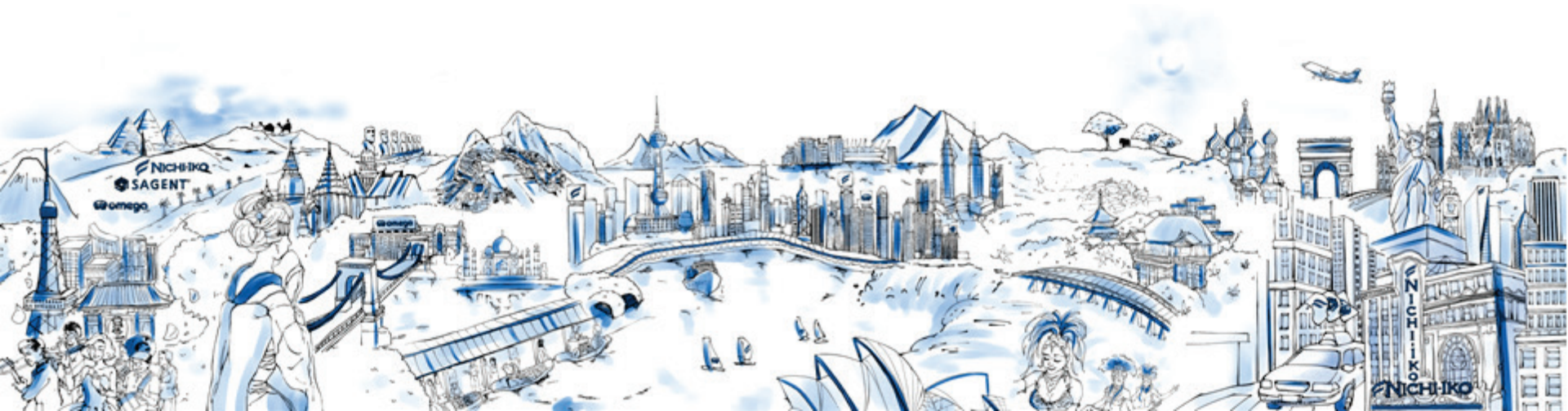
Capital Investment
8B JPY
(FY2018/3 12.7B JPY)

R&D Investment
11.5B JPY
(FY2018/3 9B JPY)

Depreciation Expenses
9.5B JPY
(FY2018/3 8.9B JPY)

Mission Statement

Our mission is to provide value-added, high quality generic products which meet the needs of patients and their families, doctors, pharmacists, wholesalers and pharmaceutical companies in the global market as one of the most respected, well established generic companies in the world.



Forward-Looking Statements

The information contained in this document is not intended as solicitation material for buying or selling the company's shares.

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