

Obelisk 2019

FY 2019/3 Presentation

Nichi-Iko Pharmaceutical Co., Ltd.

President & CEO

Yuichi Tamura



Nichi-Iko Pharmaceutical Co., Ltd.

FY 2019/3 Financial Summary (IFRS)



- ✓ Domestic generic sales increased along with market growth towards 80% generic quantitative share
- ✓ For Profit, PMP cost reduction cover effect of NHI drug price revision in Apr. 2018

Sales	(FY 2018/3 164.7B JPY) 166.5B JPY	(+) Domestic GE Volume Growth +102.9%
Core Operating Profit	(FY 2018/3 14.3B JPY) 13.3B JPY	(-) Gross Profit Decline
Operating Profit	(FY 2018/3 10.3B JPY) 8.2B JPY	(-) Impairment loss from reviewing for a value of intangible assets
Net Income	(FY 2018/3 8B JPY) 6.8B JPY	

FY2019/3 Financial Highlights by Segment (YOY)

Core Based P&L



Core Based P&L

(million JPY)	Nichi-Iko			Sagent			Consolidated		
	FY 2018/3	FY 2019/3	YOY	FY 2018/3	FY 2019/3	YOY	FY 2018/3	FY 2019/3	YOY
Sales	128,659	131,076	101.9%	36,058	35,515	98.5%	164,717	166,592	101.1%
COGS	97,816	101,321	103.6%	25,487	26,535	104.1%	123,304	127,857	103.7%
Gross Profit	30,842	29,755	96.5%	10,570	8,980	85.0%	41,412	38,735	93.5%
Gross Profit Ratio	24.0%	22.7%	-	29.3%	25.3%	-	25.1%	23.3%	-
SG&A	16,584	16,208	97.7%	6,551	5,928	90.5%	23,136	22,137	95.7%
R&D Expense	2,766	2,050	74.1%	1,701	1,453	85.4%	4,467	3,503	78.4%
Other Income	947	601	63.5%	0	2	466.9%	948	604	63.8%
Other Expense	365	378	103.5%	22	0	0.0%	387	378	97.5%
Core Operating Profit	12,073	11,720	97.1%	2,294	1,600	69.7%	14,368	13,320	92.7%
Operating Profit	12,034	11,275	93.7%	-1,733	-3,052	-	10,301	8,223	79.8%

Core Operating Profit means Operating Profit excluding Impairment of intangible assets, temporary impact of M&A and restructuring expense

Annual
Dividend
(Plan)
30.0 JPY

Capital Investment
5.0B JPY
(FY2018/3 12.7B JPY)

R&D Investment
10.8B JPY
(FY 2018/3 9.0B JPY)

Depreciation Exp.
9.4B JPY
(FY2018/3 8.9B JPY)

FY2019/3 Financial Highlights by Segment (YOY)

Reported P&L



Reported P&L

(million JPY)	Nichi-Iko			Sagent			Consolidated		
	FY 2018/3	FY 2019/3	YOY	FY 2018/3	FY 2019/3	YOY	FY 2018/3	FY 2019/3	YOY
Sales	128,659	131,076	101.9%	36,058	35,515	98.5%	164,717	166,592	101.1%
COGS	97,816	101,321	103.6%	26,097	32,113	123.1%	123,914	133,434	107.7%
Gross Profit	30,842	29,755	96.5%	9,961	3,402	34.2%	40,803	33,157	81.3%
Gross Profit Ratio	24.0%	22.7%	-	27.6%	9.6%	-	24.8%	19.9%	-
SG&A	16,584	16,575	99.9%	6,551	5,928	90.5%	23,136	22,504	97.3%
R&D expense	2,766	2,050	74.1%	1,701	1,453	85.4%	4,467	3,503	78.4%
Other Income	947	601	63.5%	0	927	-	948	1,528	161.2%
Other Expense	404	455	112.5%	3,441	0	0.1%	3,845	455	11.8%
Core Operating Profit	12,073	11,720	97.1%	2,294	1,600	69.7%	14,368	13,320	92.7%
Operating Profit	12,034	11,275	93.7%	-1,733	-3,052	-	10,301	8,223	79.8%
▼ Impairment & Integration Cost									
COGS	-	-		609	5,577		609	5,577	
Other expense, etc	39	444		3,418	Δ925		3,457	Δ479	
Total	39	444		4,028	4,653		4,067	5,097	

FY2019/3 Financial Highlights by Segment (vs Plan)

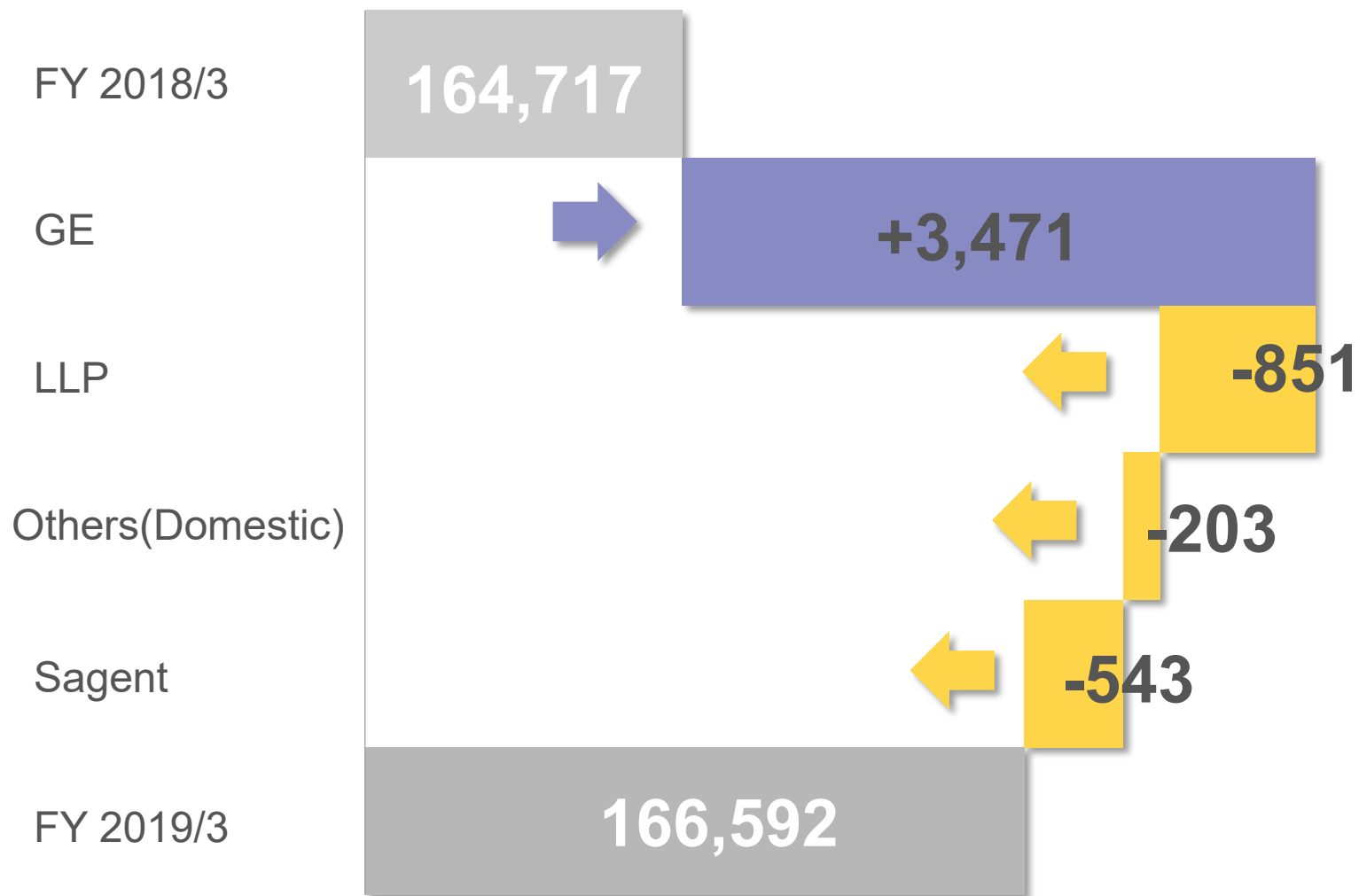


Reported P&L

(million JPY)	Nichi-Iko			Sagent			Consolidated		
	Plan	Actual	%	Plan	Actual	%	Plan	Actual	%
Sales	134,000	131,076	97.8%	36,000	35,515	98.7%	170,000	166,592	98.0%
COGS	105,000	101,321	96.5%	27,500	32,113	116.8%	132,500	133,434	100.7%
Gross Profit	29,000	29,755	102.6%	8,500	3,402	40.0%	37,500	33,157	88.4%
Gross Profit Ratio	21.6%	22.7%	-	23.6%	9.6%	-	22.1%	19.9%	-
Core Operating Profit	9,000	11,720	130.2%	500	1,600	320.0%	9,500	13,320	140.2%
Operating Profit	9,000	11,275	125.3%	500	-3,052	-610.4%	9,500	8,223	86.6%
Net Income	6,650	9,670	145.4%	350	-2,806	-801.7%	7,000	6,864	98.1%

Sales Increase/Decrease & Factor Analysis(IFRS)

(Million JPY)



Operating Profit Increase/Decrease & Factor Analysis(IFRS)

(Million JPY)

		Nichi-Iko	Sagent
FY 2018/3 Core Operating Profit	14,368	12,073	2,294
Effect of Increase/Decrease of Gross Profit	← +2,677	-1,087	-1,590
Effect of Increase/Decrease of Operating Expense, etc.	→ +1,628	733	895
FY 2019/3 Core Operating Profit	13,320	11,720	1,600
FY 2019/3 COGS Impairment	← +5,577	0	5,577
FY 2019/3 Other Operating Expense Impairment	→ +480	-374	854
FY 2019/3 Operating Profit	8,223	11,370	-3,147

Progress of Profit Management Plan

Realized Total Cost Reduction of 7.5B JPY in 2 years through Profit Management Plan from Apr.2017 to Mar.2019

Yield Rates
improvement + +

Disposal Reduction
of unfinished goods +

Disposal Reduction
of finished goods - -

Cost Reduction
of API + + +

Cost Reduction
of packaging materials +

Achieved
7.5B JPY
cost reduction

Target
6.0B JPY

Update of Strategic Alliance with Eisai



Establishment of Elmed Co., Ltd.



Elmed Co., Ltd

Apr.1, 2019

As a wholly owned subsidiary company of Nichi-Iko, Elmed Co., Ltd. was established.

Maximize profit “Amount”
by using “Volume”

1,019
Nichi-Iko Products

Production Efficiency

API Optimization

Work Efficiency

Volume
growth

187

ELMED Products

Over the next three years

2.5B JPY

Strategic Alliance with Eisai



Partnership with Eisai fully started

Based on partnership, launched IPS Information Provision & Co-Promotion

18
APIs

IPS

(Integrated Package Strategies)

**Provision of Information
Six Therapeutic Areas**

- ① Liver Cancer
- ② Breast Cancer
- ③ Epilepsy • Brain Cancer • Brain Infarction
- ④ Dementia
- ⑤ Rheumatology
- ⑥ Constipation, etc.

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Products

Co-Promotion

For main therapeutic products, manage
co-promotion to expand new generic products
Considering next options

**Nichi-Iko & Eisai Partnership
(Common business)**

- **US Market Conditions**
- **Biosimilars**

Four Main Businesses for Growth

As **Generic Injectable** for main business, made investment in SterRx and entered into **Compound Business** in 2017.

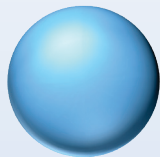
Accelerate **Biosimilar** Business and **Orphan Drug** Business under development, making a solid progress.



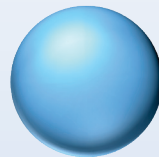
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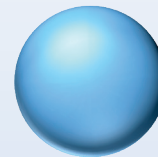
Generic Injectables



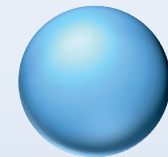
Biosimilars



Orphan Drugs



Compound Drugs



Formulations of Internal Manufacturing Capabilities for US Market (Acquisition of Raleigh Manufacturing Site)



Sagent-Raleigh Manufacturing Site

- Acquired in Feb. 2019
- FDA-approved facility (Generic Injectables & Biologics)
- Infliximab BS to be manufactured
- In-house manufacturing of out-sourced products

Location / Raleigh, North Carolina, US
Manufacturing capacities / 4M vials per year

Omega (Canada)

Generic Injectables(Liquid)

Raleigh (US)

**Biosimilars /Generic Injectables
(Lyophilization)**

Nichi-Iko Nixs

Orphan Drugs

SterRx (US)

Compound Drugs

Development Status of Biosimilar Pipeline



- Infliximab** Final stage of “Interchangeability” Phase III study in the US
- Etanercept** Approved in Mar. 2019 / Plan to launch in Nov. 2019 *Update*
- Trastuzumab** Started Phase I in the US
- Next Product** On the Evaluation for In-License From Other Parties *New*

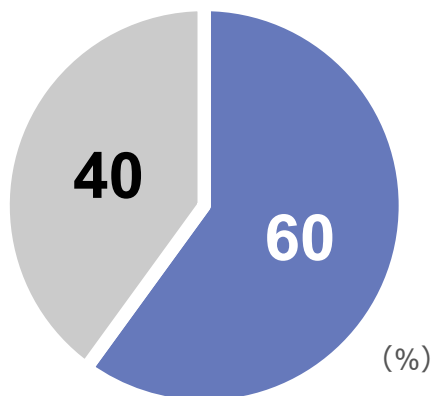
	Pre-Clinical	Phase I	Phase III	Filing/ Approval
Infliximab (Japan)	Launched (Approved in Sep. 2017)			
Infliximab (US) <i>Update</i>	Final Stage of Phase III (Plan to be filed in 2020)			
Etanercept (Japan) <i>Update</i>	Approved in Mar. 2019 / Plan to launch in Nov. 2019			
Trastuzumab (Japan, US,EU)	Started Phase I in the US			

US Market Conditions & Pipeline Progress

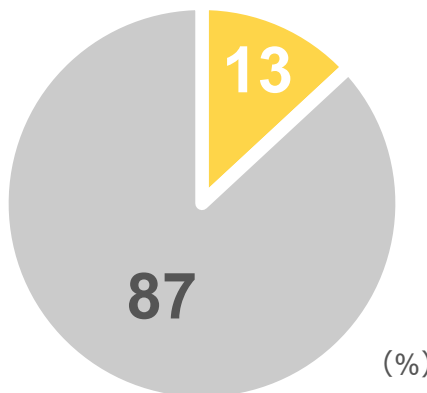
Current Sagent main products remain under strong price pressure while market price gets to stabilize.

Action Omega (Subsidiary of Sagent) in-house development & production expected to get FDA approval. Plan to get into US market from FY2021.

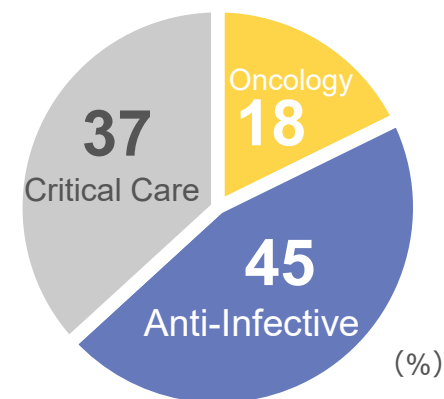
Top 10 Products Sales



Launched Products Sales in FY2019/3



Sales by Areas



	FY2018/3	FY2019/3	FY2020/3 (E)	FY2021/3 (E)
Number of Product Launched/to be Launched	13	12	8-12	8-12

FY 2019/3 Forecast (IFRS)

(million JPY)	FY 2019/3		FY 2020/3					
	Full Year		H1 Forecast		H2 Forecast		Full Year Forecast	
	Consolidated	Sagent	Consolidated	Sagent	Consolidated	Sagent	Consolidated	Sagent
Sales	166,592	35,515	98,000	17,000	103,000	19,600	201,000	36,600
Gross Profit	33,157	3,402	19,600	4,000	20,900	4,700	40,500	8,700
Core Operating Profit	13,320	1,600	3,100	100	5,400	100	8,500	200
Operating Profit	8,223	-3,052	3,100	100	5,400	100	8,500	200
Net Income	6,864	-2,806	3,200	50	3,800	50	7,000	100

FY2020/3 Exchange rate : 108.0 JPY/\$

Annual
Dividend
(Planned)
30 JPY

Capital Investment
9.0B JPY
(FY 2018/3 5.0B JPY)

R&D Investment
10.5B JPY
(FY 2019/3 10.8B JPY)

Depreciation Exp.
7.6B JPY
(FY 2019/3 9.4B JPY)

Mission Statement

Our mission is to provide value-added, high quality generic products which meet the needs of patients and their families, pharmacists, doctors, 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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Accordingly, actual results may differ from forecasts for a variety of reasons.

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