



FY2020/3 Presentation

May 2020

**Nichi-Iko Pharmaceutical Co., Ltd
President & CEO
Yuichi Tamura**



Nichi-Iko Pharmaceutical Co., Ltd.

1

Implementation of measures to prevent spread of COVID-19

Implemented measures to prevent the spread of COVID-19 virus, considering the status of infections in Japan and overseas and the views of governments and experts

Working system for domestic employees (including Temporary staff) [All Prefectures in Japan]

- **Super Flextime** (=Non-core flextime)
- **Granting special paid leave** (Parents of children from elementary schools and special needs schools)
- **To ensure social distancing**, distribution of business locations among departments to reduce contact density.

In addition, our company stipulate measures to prevent the spread of COVID-19 infections, visits to medical institutions, responses in poor health conditions and responses to the occurrence of infectious persons and close contacts with infectious persons.

10 production sites (7 sites in Japan, 3 sites in North America) are in normal operation.

We will continue to place top priority on the health and safety of our business partners and our employees and their families in preventing the spread of COVID-19 infections.

2

Cooperation for clinical researches

Nichi-Iko provides Futhan® and Camostat Mesilate free of charge to contribute domestic and overseas clinical trials

- ◆ **Tokyo Univ.** starts clinical trials of COVID-19 → [Tokyo Uni. Press Release](#)
- ◆ **Oxford Univ. · Edinburgh Univ.** collaborative clinical research → [Latus Therapeutics News](#)

3

Capital expenditure in Aichi Plant to expand Futhan®

4

Manufacturing expansion of AVIGAN®

As per request made by Fujifilm and Toyama prefecture, the company decided to manufacture AVIGAN® tablets as a subcontractor

5

Comprehensive Partnership Agreement

The company has donated Pure Hand Gels (hand sanitizer) and delivered lecture sessions about infection prevention

Consolidated results increased in sales and decreased in profit

(Sales increased due to Elmed integration, but profits decrease due to various expenses)

◆ Nichi-Iko Group increased in sales and decreased in profit

(Though Elmed contribution, decreased in profit due to drug price revisions)

◆ Sagent Group decreased in sales & profit

(Indian supplier issues offset by new product introductions; advanced pipeline investment for the future)

Sales	(FY 2019/3 166.5 B JPY) 190.0 B JPY	(+) Domestic Generic Sales 119.4% (-) US Market Sales Growth 99.0% (+) Sales Increase from Elmed Integration
Core Operating Profit	(FY 2019/3 13.3 JPY) 8.0 B JPY	(+) Improve along with Domestic Sales Growth (-) Decline of gross profit margin due to NHI Drug Price Revision (-) R&D Investment in US
Net Income	(FY 2019/3 6.8 JPY) 5.1 B JPY	(+) Gain on sales & valuation of Aprogen Shares (-) Impairment in Sagent (-) Voluntary recall costs (-) Loss on sales of Trastuzumab

average exchange rate(PL)				JPY/USD	year-end exchange rate(BS)				JPY/USD
FY 2019 Q1	109.90	FY 2019 Q3	108.76	今期予算レート 108.00	6/2019	107.79	12/2019	109.56	
FY 2019 Q2	107.35	FY 2019 Q4	108.92		9/2019	107.92	3/2020	108.83	

FY2020/3 Performance by Segment (YoY)



YoY

(Million JPY)	Nichi-Iko Group				Sagent Group				Consolidated				Plan
	FY 2019/3	FY 2020/3	Variance	YoY	FY 2019/3	FY 2020/3	Variance	YoY	FY 2019/3	FY 2020/3	Variance	YoY	
Sales	131,076	154,912	23,836	118.2%	35,515	35,163	-352	99.0%	166,592	190,076	23,483	114.1%	194,000
COGS	101,321	126,875	25,553	125.2%	32,113	25,881	-6,231	80.6%	133,434	152,756	19,321	114.5%	155,000
Gross Profit	29,755	28,037	-1,717	94.2%	3,402	9,282	5,879	272.8%	33,157	37,319	4,162	112.6%	39,000
SG&A	16,450	19,670	3,219	119.6%	6,054	5,944	-109	98.2%	22,504	25,614	3,110	113.8%	-
R&D expense	2,050	2,431	380	118.6%	1,453	1,830	377	125.9%	3,503	4,261	758	121.6%	-
Other income	571	310	-261	54.3%	957	-6	-963	-0.6%	1,528	303	-1,225	19.8%	-
Other expense	455	2,465	2,010	541.8%	0	2,407	2,407	-	455	4,873	4,417	1071.0%	-
Core Operating Profit	11,745	6,980	-4,765	59.4%	1,575	1,040	-535	66.0%	13,320	8,500	-5,300	63.8%	8,500
Operating Profit	11,370	3,780	-7,590	33.2%	-3,147	-907	2,240	-	8,223	2,873	-5,349	34.9%	-

Interim Dividend
(Planned)

30.0 JPY

Capital Expenditure

8.4 B JPY

(FY/2019 5.0 B JPY)

R&D Investment

13.7 B JPY

(FY/2019 10.0 B JPY)

Depreciation

11.8 B JPY

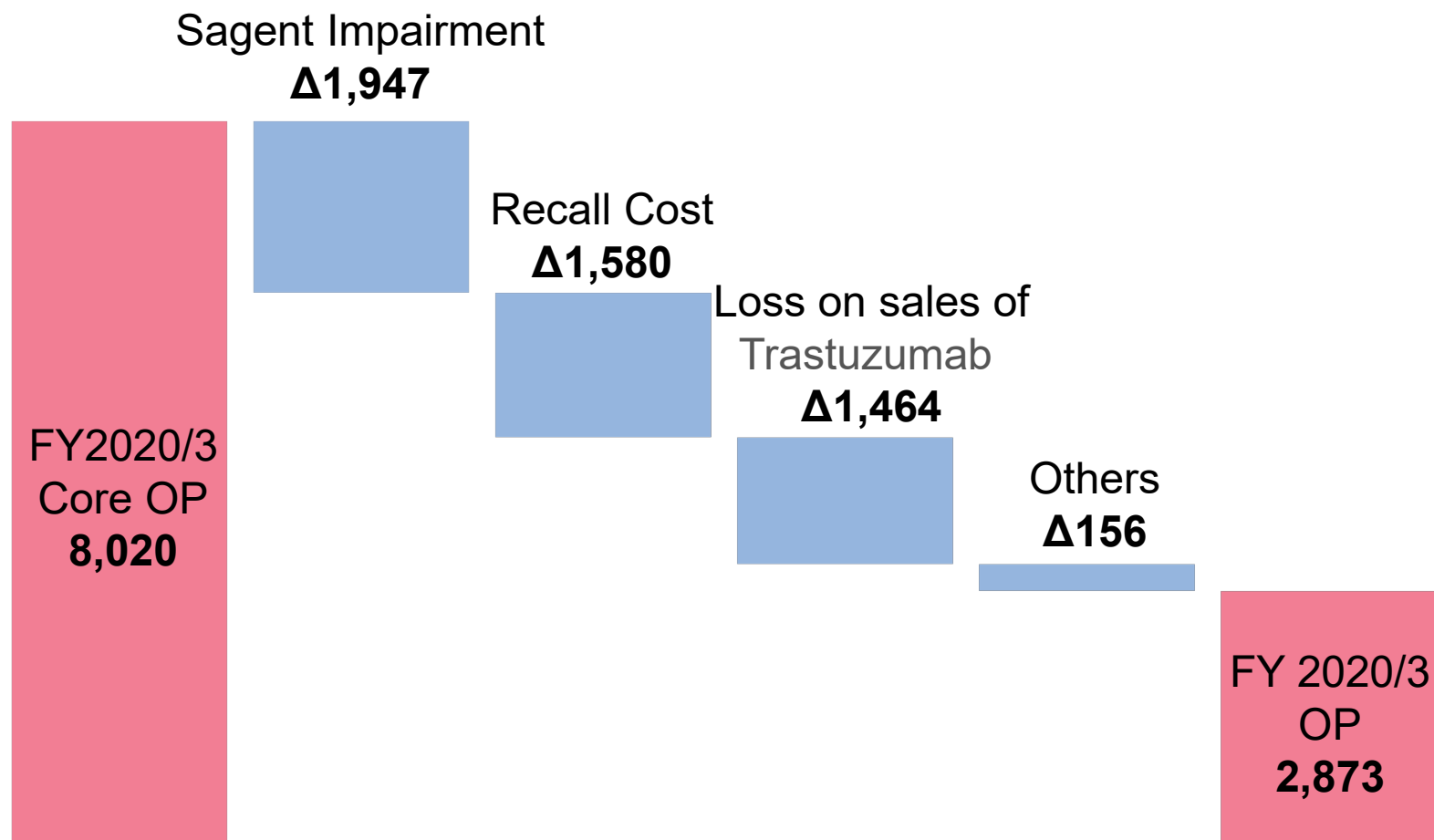
(FY/2019 9.4 B JPY)

Sales Change Factors & Analysis (IFRS)



Gap between Core Operating Profit & Operating Profit

(Million JPY)



Domestic (Nichi-Iko Segment) Sales Trend

Risks

Growth Risks

1. Drug price revision

Apr 2018 Δ12.6%

Oct 2019 Δ7.6%

Apr 2020 Δ3.1%

<Revision range is gradually shrinking>

2. Gx penetration target

The target Gx use rate of 80% will be achieved in Sep 2020



Growth Potential

Growth Drivers

1. Blockbusters' patent to be expired

FY2021 **¥440 B**

• Apr 2020 approval <Eldecalcitol>

FY2022 **¥220 B**

FY2023 **¥290 B**

※ Rx market size where we are entering, calculated in sales value

※ The sales of Pregabalin are not included



2. Decline in entrants

Sales at proper price

Only One Gx Development

• Feb 2020 approval <Pirfenidone>

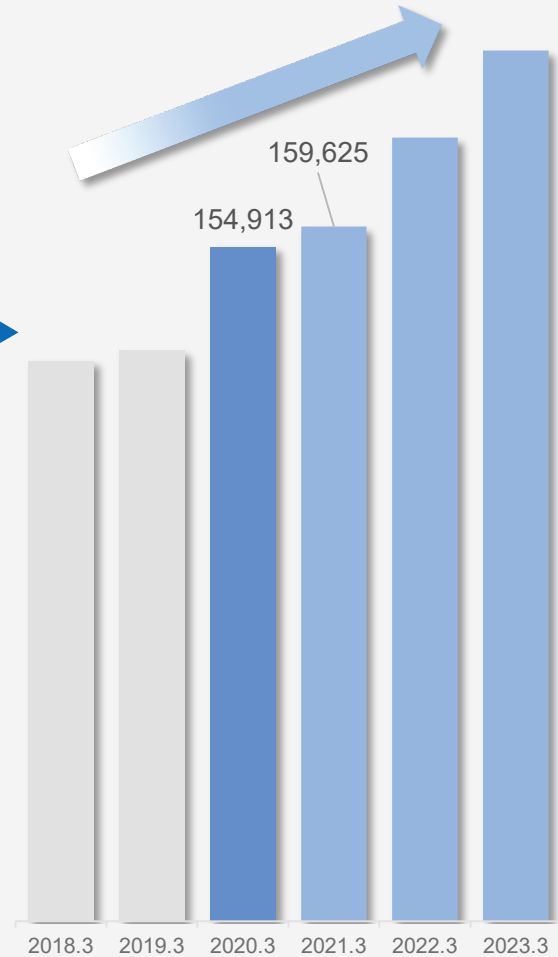
3. Formulary

Drug makers having certain level of supply capability will be further selected for prescription

4. Biosimilar

With awaiting for promotion policies to be implemented, we are expanding our BS portfolio

Sustainable growth can be made even after exceeding 80%



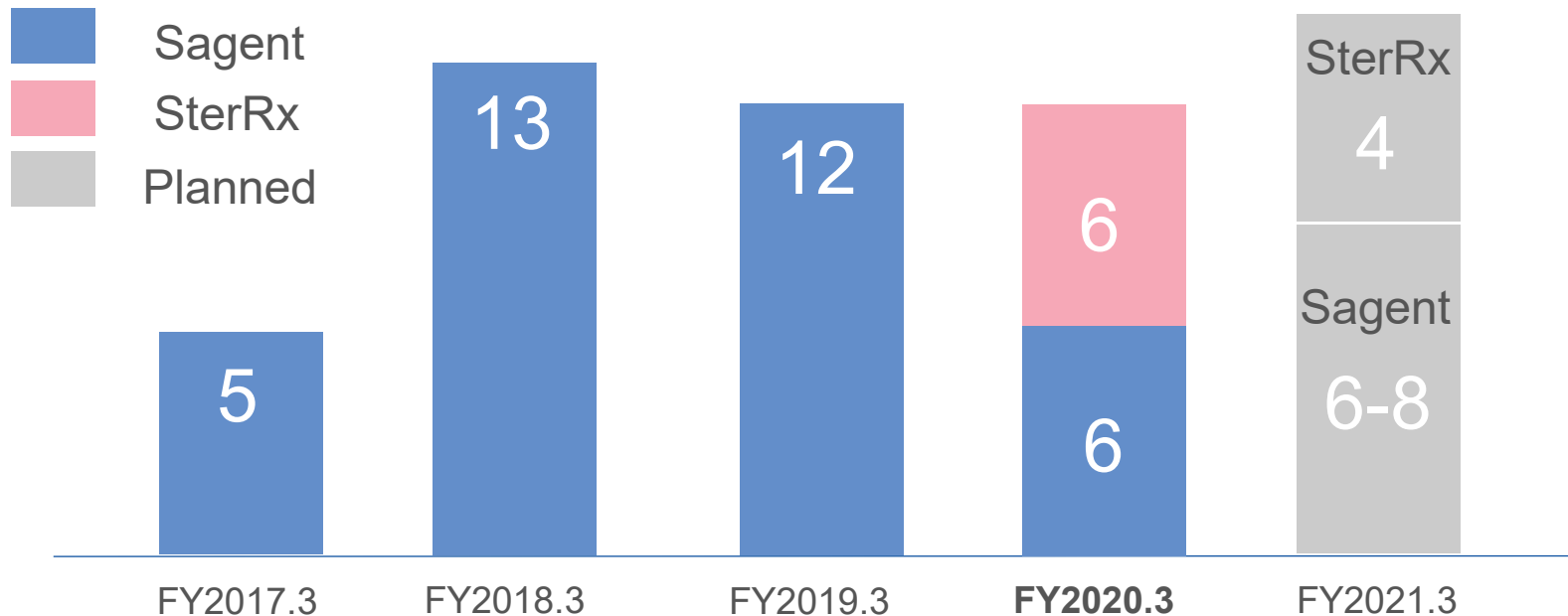
Sagent recording strong sales for Fulvestrant

- ✓ Launched 6 products and 6-8 new products to be launched in FY3/2021

SterRX expanding new product line-up

- ✓ Launched 6 products and expect 4 new products to be launched in FY3/2021

Product launches



FY3/2020

FY3/2021

FY3/2022

<India supplier Issue >

13 products affected

Sales Δ **3B**_{yen}

Supply reintroduction

5-6 products

Supply reintroduction

5-6 products

In-house production schedule

1 product

Omega Montreal
Filed in FY3/2020

4~5 products
Sagent Raleigh to file
in FY3/2021 and FY3/2022

4~7 products
Omega Montreal to file
in FY3/2021 and FY3/2022

Infliximab BS

2020 Phase 3 completed

CY2021 to file FDA, CY2022 approval expected

<Delay in scale-up production due to Covid-19>



BS strategy shift

Trastuzumab (Herceptin®)

▶ Bevacizumab (Avastin®) Phase 3

To enter Japanese market as a third player in Nov. 2021



Product	Market	Market Potential (JPY B)	Pre-Clinical	Phase I	Phase III	Filing/Approval
Infliximab	US	4,000	Phase III Done			Plan to file in CY 2021
Bevacizumab	Japan	950	Plan to file in Nov, 2020			Plan to file in Nov,2020

FY 2021/3 Forecast (IFRS)



(million JPY)	FY 2020/3			FY 2021/3								
	Full year			Full year forecast								
	Nichi-Iko Group	Sagent Group	Consolidated	Nichi-Iko Group	Variance	YoY	Sagent Group	Variance	YoY	Consolidated	Variance	YoY
Sales	154,912	35,163	190,076	159,000	+4,088	102.6%	40,000	+4,837	113.8%	199,000	+8,923	104.7%
Gross profit	28,037	9,282	37,319	29,500	+1,463	105.2%	9,000	-282	97.0%	38,500	+1,180	103.2%
Core operating profit	6,980	1,040	8,020	7,500	+519	107.4%	0	-1,040	0.0%	7,500	-520	93.5%
Net Income			5,133							5,200	+66	101.3%

Interim Dividend
(Planned)

30.0 JPY

Capital Expenditure

9.3 B JPY

(FY/2019 8.4 B JPY)

R&D Investment

11.4 B JPY

(FY/2019 13.7 B JPY)

Depreciation

11.2 B JPY

(FY/2020 11.8 B JPY)

Progress of The 8th Med-Term Management Plan



Strategy1

Further deepening and evolution of business fields

- **Strategic Alliance & Joint Venture with Medpeer**

Strategy2

Pursuit optimization of operation

- **Cost Synergy from PMP8**

Strategy3

Enhance competitiveness and assure the global standard quality

- **Sagent Business Expansion (Biosimilars, compound business, orphan drugs)**

Strategy4

Ensure reliability as a life science company based on ESG activities

- **Regional Comprehensive Collaboration Agreement**

『kakari for Clinic』 Business Alliance

『kakari for Clinic』 is a family clinic support service that connects patients and clinics. A joint venture with Medpeer is scheduled to start in September 2020 aim to promote joint business. Contributing to solving social issues through health techs such as “Online Medical Care” and “Online Medication Advice”



Deregulation of Online Medical Care & Medication Guidance

- Conduct online medical care at doctor's discretion
- Medical institutions fax prescriptions to pharmacies
- Pharmacy sends the prescription drugs to patient's home
- Pharmacists Online Medication Advice



Clinic PR	Interactive chat	Medical service reservation
Online medical service	Prescription data sending	Other functions



Prescription data sending	Medication consultation	Medication follow-up	Electronic drug handbook
Online medication Advice	Gx difference reporting	Deglutition support	Electronic Payments

Expect cumulative cost savings of at least 15 billion yen over the 3-year period ending March 2022

➤ Going steady at present

1	Yield rate
2	Intermediate product disposal
3	Finished product disposal
4	API procurement cost
5	Outsourcing production cost
6	Purchasing cost
7	PMI (integration effect of facility & API)
8	PMI (integration effect of developed products)

PMP 8

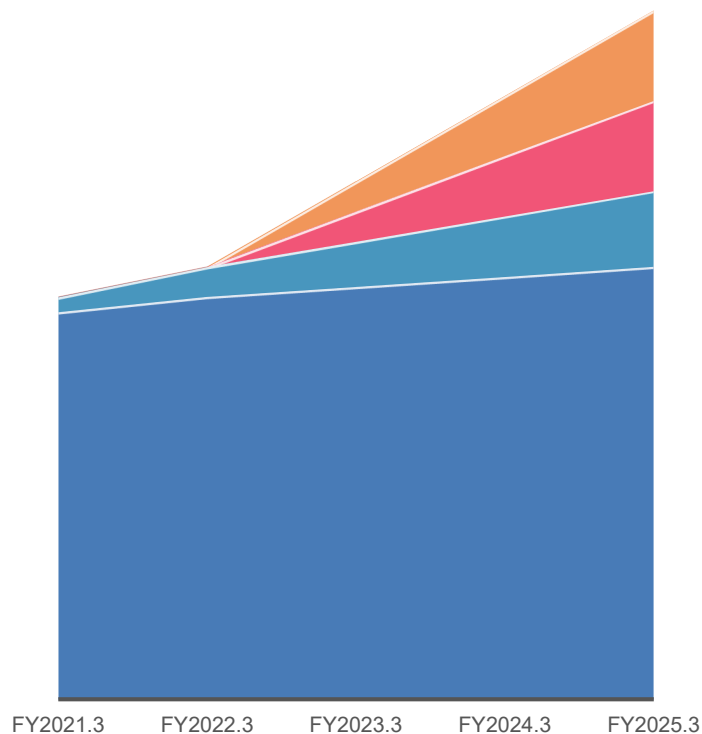
4.4 B JPY

(as of End of March 2020)

15.0 B JPY

(cumulative 3 years)

As generic injectable for main business, accelerate biosimilar, orphan drug, compound businesses



1. Biosimilar

Focus on infliximab FDA filing, and expand line-up

2. Orphan drug

Clinical trials expanded to include Eastern Europe as well as the US to achieve faster entry into market

3. Compound

Steady line-up growth, increased production

4. Generic

Focus more on in-house production (Raleigh, Omega)

Comprehensive Partnership Agreement

Nichi-Iko Group has concluded comprehensive partnership agreements with 10 cities in Japan aiming to tackle local society issues which can be solved only by pharma company



Namerikawa-shi 2019/08/23

Matsudo-shi 2019/08/30

Toyama-shi 2019/11/08



Imizu-shi 2019/12/06

Takaoka-shi 2020/01/17

Inabe-shi 2020/02/12



Matsuzaka-shi 2020/02/12

Tomakomai-shi 2020/03/24

Nonoichi-shi 2020/03/26

Kitahiroshima-shi 2020/04/09



Mission Statement



We shall excel
as the outstanding generic pharmaceutical
company,
making every effort to continue to serve and deliver
our products needed by our patients and their
families, pharmacists, doctors, distributors and
other pharma companies around 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.

Earnings forecasts and other future forecasts contained herein have been made by the company based on information available at the time the material was compiled and encompass potential risks and uncertainties.

Accordingly, actual results may differ from forecasts for a variety of reasons.

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