



# **FY2021/3 Presentation**

**May 2021**

**Nichi-Iko Pharmaceutical Co., Ltd.**

**President & CEO**

**Yuichi Tamura**



**Nichi-Iko Pharmaceutical Co., Ltd.**

# 5 Initiatives to improve production management and quality control

## 5 Initiatives

- (1) Thorough GMP compliance at Toyama Plant 1**
- (2) Securing data integrity and achieving synchronous and timely testing**
- (3) Enhanced compliance by execution of thorough audit on each plant as a manufacturing & marketing authorization holder**
- (4) Formulation of Nichi-Iko Group's new quality policy "Our Pledge of Trust and Confidence", shared by all managers and employees**
- (5) Newly established Pharmaceutical Technology Division**

# 5 Initiatives to improve production management and quality control

## (1) Thorough GMP Compliance at Toyama Plant 1

**Basis of “production mgmt. & quality control”**

**GMP: Approval requirement of “Manufacturing & Marketing License”**

**GMP  
Compliance**

Revised OOS management procedures &  
Revised deviation handling procedures



Expanded GMP  
education & training

**GMP Audit  
Office  
(new org.)**

Deviation monitoring, Guidance for GMP records  
Audit on execution status of stability studies  
Nation-wide plant audit by external GMP consultants

**Board  
members**

Empowering the Manager for Drug Manufacture,  
and compulsory reports from the position  
Reports from GMP Audit Office

# 5 Initiatives to improve production management and quality control

## (2) Securing data integrity and Achieving synchronous and timely testing

**Data integrity: All data is available  
with no defects and inconsistency**

**Real-time data acquisition from  
manufacturing machines (SCADA)**

**The manufacturing execution system  
(MES) synchronized with SCADA**

**Intro. of the  
production  
management systems**

Use of **the quality control system (LIMS)**

**Use of the quality  
control system**

Additional QC employee staff  
Additional test devices & equipment

**Improvement of  
quality-related testing  
capability**

# 5 Initiatives to improve production management and quality control

## (3) Enhanced compliance by execution of thorough audit on each plant as a manufacturing & marketing authorization holder

### Thoroughly executed audits

	Toyama Plant 1	Toyama Plant 2	Aichi Plant	Shizuoka Plant	Yamagata Plant	Saitama Plant	Yakuhan Pharma
Audit in this fiscal year	Every month since Apr. 2020	Oct. 2020	Sep. 2020	Sep. 2020	Oct. 2020	Oct. 2020	Oct. 2020



### QA & Pharmacovigilance Div.



# 5 Initiatives to improve production management and quality control

## (4) Formulation of Nichi-Iko Group's new quality policy “Our Pledge of Trust and Confidence”, shared by all managers and employees

1. Effective on Jul. 15, 2020
2. Defined the company anniversary of foundation (Jul. 15) as “**Nichi-Iko's Quality Day**”
3. All employees read out the quality policy in meetings and morning gatherings, to re-recognize “quality first” everyday
4. Each dept. and div. sets quality improvement targets and specific measures, and reports the progress at the management conference every month
5. Every employee shares the view that this issue happens not only in the plant. All employees believe that we all are a part of this issue and the problems are our own.
6. Keep disclosing the important measures and activities related to this issue on the Nichi-Iko's website.

# 5 Initiatives to improve production management and quality control

## **(5) Newly established Pharmaceutical Technology Division (since Apr. 2021)**

Role: Centrally address “integration”, “improvement” and “optimization” of the existing products, handling from strategy formulation to on-site execution

### **<1> Production optimization among plants in Toyama, Gifu and Aichi**

Formulate plans for establishing stable supply structures, considering a capacity and characteristics of each plant

### **<2> Drive improvement measures for all existing products (both solid dosage form and injections)**

Assess and prepare transition plans for stably-suppliable products and build up stable supply systems, prioritizing the products produced at Toyama Plant 1

### **<3> Track and manage the progress of related issues, as the secretariat of the Stable Supply Committee**

Promote quality improvement measures and activities, and manage the progress

# Risk assessment on quality and resumed production at Toyama Plant

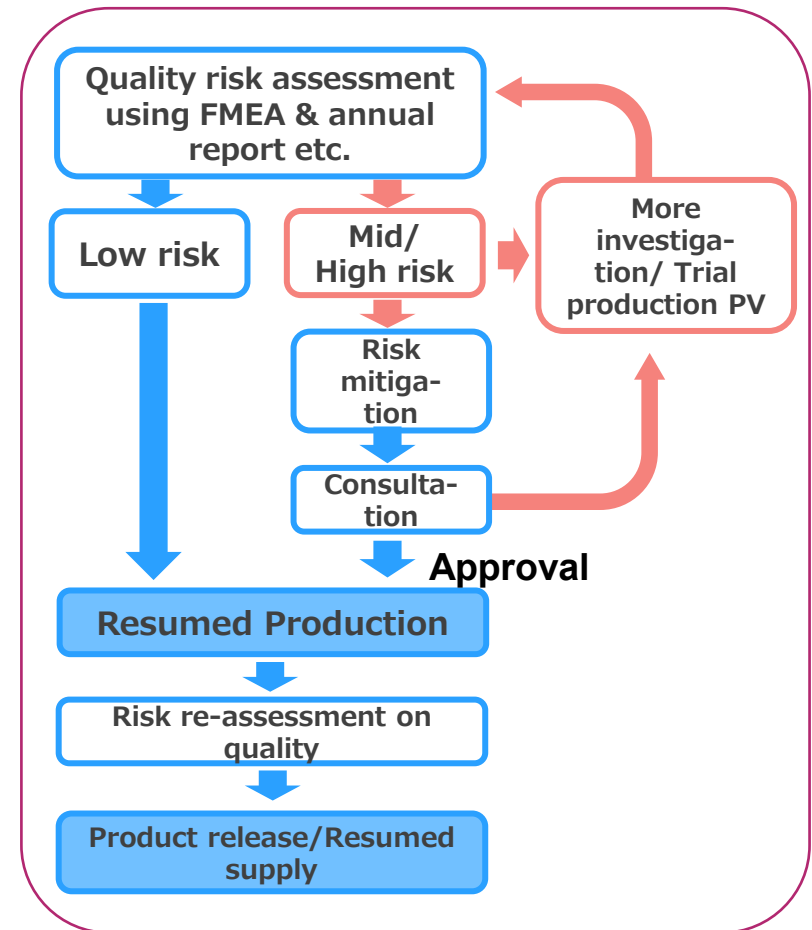
## [Risk Assessment using FMEA]

### [Assessment Points]

- (1) Match between SOPs, instruction records and approval doc.
- (2) Robustness of production methods
- (3) Robustness of quality test methods
- (4) Robustness of product release tests
- (5) Review current production method validation
- (6) Development data, technical transfer materials
- (7) Stability study results
- (8) Validity of product release standards
- (9) Control status of drug substances

### [Assessment Method]

For each assessment item, evaluate by a point system on “Impact on quality”, “Probability” and “Detection rate” and calculate Risk Priority Number (RPN)



- ◆ Perform risk assessment of all 343 products at Toyama Plant 1 by the end of May
- ◆ Completed risk assessment of Gifu plant
- ◆ Perform risk assessment of other plants (incl. Aichi, Shizuoka, Saitama, Yamagata, Yakuhon) by the end of Jun.
- ◆ Disclose information on risk assessment for the product release to be resumed



# Status of Resumed Product Release – Updated on Nichi-Iko Website



<https://www.nichiiko.co.jp/>

一般の皆さまへ

医療関係者の皆さまへ

株主・投資家の皆さまへ

日医工について

CSR

採用情報

ホーム > 医療関係者の皆さまへ

MEDICDAL

医療関係者の皆さまへ

医薬品と医業経営コンサルタント認定者により、  
医療の現場を多角的にサポートしています

重要

自主回収に関する重要なお知らせ（製造販売元 日医工、ヤクハン製薬）

供給状況に関するお知らせ



Go to “Medical practitioners’ section”  
Click “Supply Status Report”

# Status of Resumed Product Release – Updated on Nichi-Iko Website

## 供給状況に関するお知らせ

### Supply Status Report

<https://www.nichiiko.co.jp/>

2021年4月22日

製品供給に  
関するお知らせ



対象製品の状況  
(2021年5月10日現在)



Download the  
product list with  
the supply status

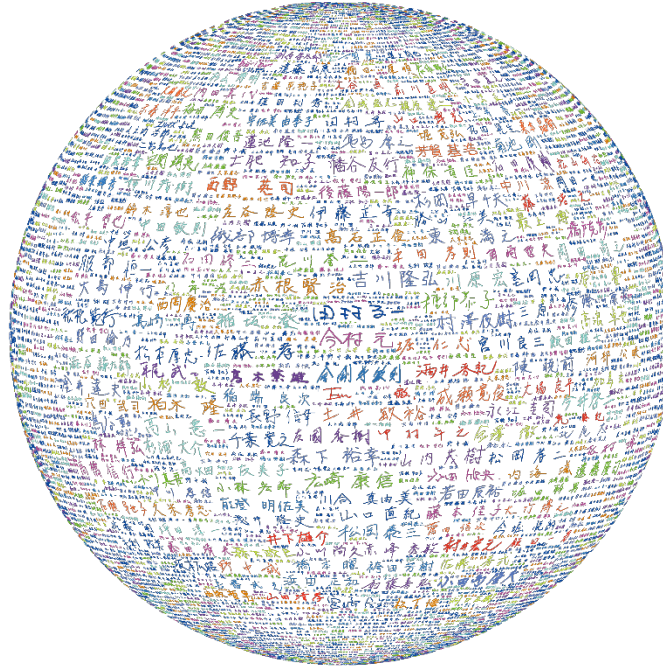
### Product list with product release status

This status list will be updated accordingly.

\*3 as shown in the following table: “Product release” column shows only expected timing; hence they are subject to change. “TBD” means the products will take a longer time to complete assessment before product release.

No.	Product name	Alternative products	MAH of alternative	Assessment complete	Product Release*3	Update
1	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	
2	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	
3	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	
4	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	
5	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	
6	〇〇錠〇mg「日医工」	〇〇錠〇mg「□□」	□□	2021年〇月	2021年〇月	

## Create a system for safety and reliability



One Heart  
One Vision  
**ONE NICHI-IKO**

## Lower sales and profits on a consolidated basis

**Nichi-Iko Group**

decreased in sales and profits

Impacted by drug price revision in Oct. 2019 & Apr. 2020,  
Less product line-up by voluntary recalls and of Elmed,  
Delayed sales grow of additional listed products

**Sagent Group**

increased in sales but decreased in profits

Sales up by sales growth of COVID-19  
related products

<b>Sales</b>	(YOY 190.0B JPY) <b>188.2B JPY</b>	(-) Domestic sales YOY 98.1% (+) US sales YOY 103.2% (-) Sales down in Elmed products impacted by other company
<b>Operating Profit</b>	(YOY 2.8B JPY) <b>100M JPY</b>	(+) Contribution to profits by the additionally listed products in Jun. & Dec. 2020 (-) Drop in gross profit margin due to the listed drug price revisions (rate of price reduction: - 10.7%) (+) Recognition of the economical purchase gain (12.2B JPY) (-) Posting of various one-time expenses incl. recall costs (13.1B JPY) (-) Front costs for in-house manufacturing in the U.S.
<b>Net Income attributable to parent</b>	(YOY 5.1B JPY) <b>- 4.1B JPY</b>	(-) Recorded a gain on sales of Aprogen's shares in the previous FY. (6.3B JPY) (-) Disposal of deferred tax assets (4.1B JPY)

# FY2021/3 Results by Segment

(Closing base)

(Million JPY)	Nichi-Iko Group				Sagent Group				Consolidated			
	FY 2020/3	FY 2021/3	Variance	YOY	FY 2020/3	FY 2021/3	Variance	YOY	FY 2020/3	FY 2021/3	Variance	YOY
Sales	154,912	151,929	-2,983	98.1%	35,163	36,289	+1,126	103.2%	190,076	188,218	-1,857	99.0%
COGS	126,875	133,763	+6,888	105.4%	25,881	33,210	+7,328	128.3%	152,756	166,973	+14,217	109.3%
Gross Profit	28,037	18,166	-9,871	64.8%	9,282	3,079	-6,202	33.2%	37,319	21,245	-16,074	56.9%
SG&A	19,670	20,740	+1,070	105.4%	5,944	6,288	+344	105.8%	25,614	27,029	+1,414	105.5%
R&D Expense	2,431	2,213	-217	91.0%	1,830	2,122	+291	116.0%	4,261	4,335	+74	101.7%
Other Income	310	12,990	+12,680	4190.3%	-6	-28	-21	466.7%	303	12,962	+12,658	4277.9%
Other Expense	2,465	1,642	-823	66.6%	2,407	1,092	-1,314	-	4,873	2,734	-2,138	56.1%
Core Operating Profit	6,980	2,995	-3,985	42.9%	1,040	-2,017	-3,057	-	8,020	977	-7,043	12.2%
Operating Profit	3,780	6,560	+2,779	173.5%	-907	-6,452	-5,545	-	2,873	107	-2,766	3.7%

Annual dividend (plan)  
**25.0 JPY**

Capital Expenditure  
**9.6B JPY**  
(FY2020/3 8.4B JPY)

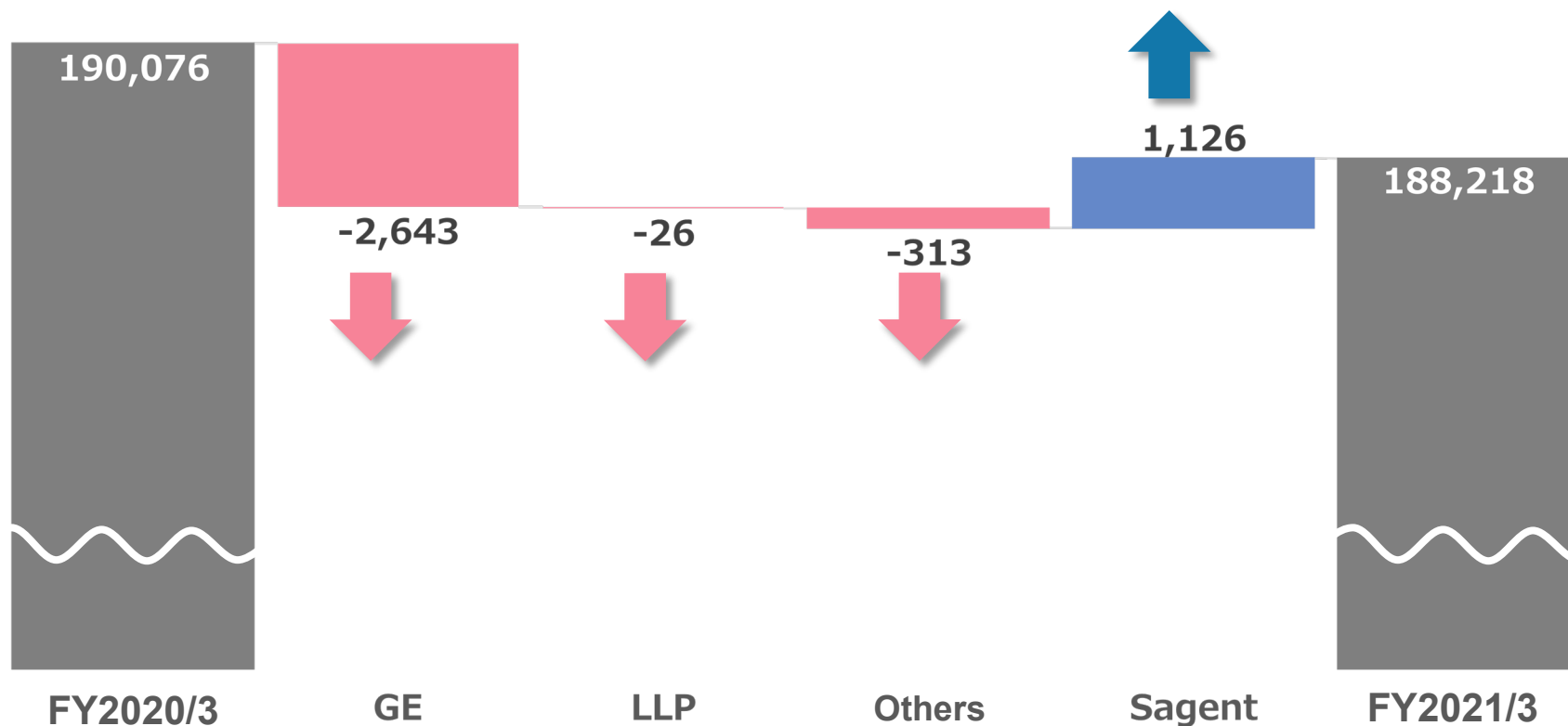
R&D Investment  
**13.5B JPY**  
(FY2020/3 13.7B JPY)

Depreciation  
**13.2B JPY**  
(FY2020/3 11.8B JPY)

Reduction of executive compensation to clarify management responsibility for business results for the fiscal year ending March 2021  
 President & CEO : Monthly remuneration 50% reduction / Full-time director : Monthly remuneration 30% reduction  
 Senior Vice President : Monthly remuneration 10% reduction

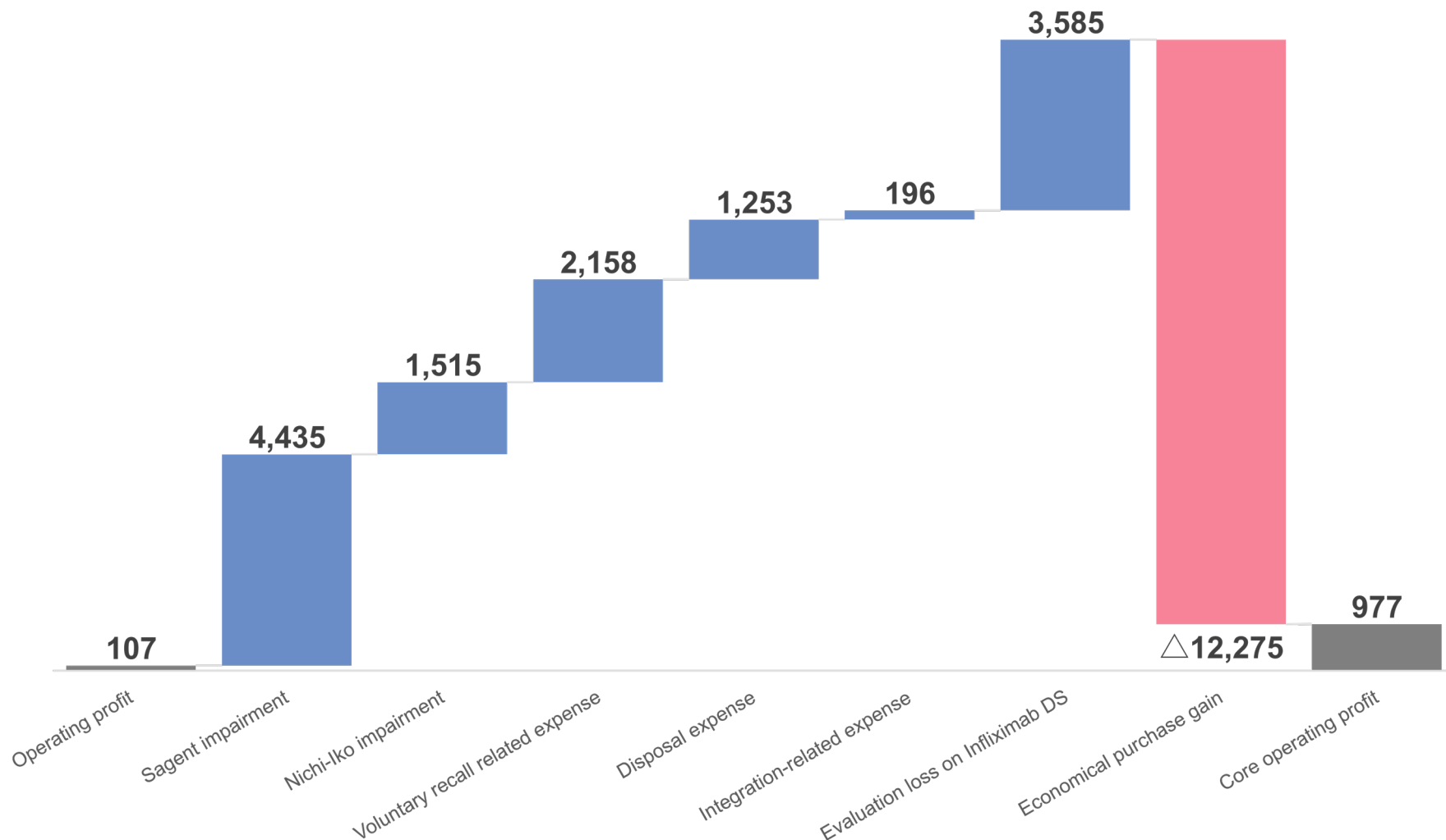
# Sales Change Factors & Analysis (IFRS)

(Million JPY)



# Gap of Core Operating Profit & Operating Profit

(Million JPY)



## Infliximab BS (US)

2020: Completed Phase III  
Secured the data for  
Interchangeability



**2023: Schedule to file for FDA**  
(Impacted by COVID-19)

- Technology transfer delayed
- FDA approval activities in the partner Korean plant delayed

## Bevacizumab BS (Japan)

2020: Scheduled to file for PMDA  
in Nov. 2020 using overseas data



**2022: Scheduled to launch**

Generic name	Market Size (100M JPY)	Pre-clinical	Phase I	Phase III	Filing & Approval
Infliximab	USA	4,000	Phase III completed		<b>2023</b> Schedule to file
Bevacizumab	Japan	950	Utilize the overseas clinical data		<b>Nov. 2020</b> Filed



## < CAMELOT >

**CAMostat Efficacy vs. pLacebo for Outpatient Treatment of COVID-19**

Phase II study aimed to evaluate the safety and efficacy of camostat mesilate for the treatment of high-risk outpatients with positive COVID-19

Phase II completed, CSR in-progress

## < ACTIV-2 >

**Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

Clinical study of the therapeutic drugs for COVID-19 outpatients, supported by NIAID (National Institute of Allergy and Infectious Diseases)

Phase II completed, NIAID is currently analyzing data

## A Dose Ranging Study Evaluating Efficacy and Safety of NI-03 (TACTIC)

Link : <https://clinicaltrials.gov/ct2/show/results/NCT02693093>

### Phase II

- ◆ Investigated ingredient: Camostat mesilate  
For rare disease
- ◆ Total patient enrollment (target): 260
- ◆ Patient enrollment (plan) by region:  
USA 130 & / Eastern Europe 130
- ◆ Scheduled filing timing: in 2022

# FY2022/3 Full Year Forecast

(Million JPY)	FY2021/3: Actual			FY2022/3: Forecast		
	Nichi-Iko Group	Sagent Group	Consolidated	Nichi-Iko Group	Sagent Group	Consolidated
Sales	152,481	36,289	<b>188,770</b>	153,000	42,000	<b>195,000</b>
Core Operating Profit	2,995	-2,017	<b>977</b>	2,000	500	<b>2,500</b>
vs Sales	2.0%	-5.6%	0.5%	1.3%	1.2%	1.3%

## Nichi-Iko Group

- (+) Additional sales by Gifu Plant
- (-) Less product line-up for Elmed (used to be produced by Kobayashi Kako)
- (-) Impact of price revision
- (-) Less product release due to risk assessment by Toyama Plant 1
- (+) Synergy achieved by integrated product line-up within Nichi-Iko Group
- (+) Further cost reduction measures
- (+) Reshaping cost structure

## Sagent Group

- (+) SterRx: Line expansion & Sales volume increase
- (+) Raleigh: Sales up in CMO business and in-house manufacturing in the U.S.
- (+) Large number of launch products (15 to 20 new products)
- (±) Impact of COVID-19
- (-) Uncertain price trends

Annual dividend  
(planned)

**20.0 JPY**

Capital  
Expenditure

**10.9B JPY**

(FY2021/3 9.6B JPY)

R&D Investment

**12.6B JPY**

(FY2021/3 13.5B JPY)

Depreciation

**10.6B JPY**

(FY2021/3 13.2B JPY)

# 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.

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