



FY2022/3 H1 Presentation

November 2021

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



Nichi-Iko Pharmaceutical Co., Ltd.

Message from CEO

Since April 2021, we have been thoroughly and cautiously performing quality assessment of all products to be manufactured and released by Toyama Plant 1, using FEMA and other methods.

We have resumed our production and product release successively, but it is taking longer than expected.

This situation has translated into the delays in release of many products, and has caused many patients and people working at medical institutions, wholesalers and other pharmaceutical companies, a great deal of inconvenience such as stockouts.

At the outset of this meeting, we would like to sincerely express our deepest apology about our product supply status.

Furthermore, we would like to apologize to our shareholders from the bottom of our heart about the full year performance forecast largely revised downward this time.

President and CEO
Yuichi Tamura

Nichi-Iko Group as a whole, continuously have executed the **15** projects to improve our manufacturing and quality management systems.

Quality Policy of
Nichi-Iko Group
– Pledge of Trust
and Confidence

Appointment of
Director in
charge

Thorough
employee
training

Appropriate
allocation of
corporate
resource

Organizational
structure

Production with
sufficient human
resources

Intro. of the
production
mgmt & quality
control systems

Strengthened
GMP inspection
scheme (internal
& external)

Quality risk
management

Review gap of
approved & actual
manufacturing
process

Review &
clarification of
SOPs

Review of
production &
test records

Tightened
product release
approval

Weekly update
on release status
from Toyama
Plant 1

Review of the
whistleblowing
system

Lower sales and profits on a consolidated basis

Nichi-Iko Group:
Decrease in sales & profits

Impacted by drug price revision in Apr. 2021.
Gifu Plant products offset the lower number of products released from Toyama Plant 1. But decreased sales of Elmed products, supplied by Kobayashi Kako etc. resulted in an overall decrease in sales.

Sagent Group:
Increase in sales & profits

Increase in sales due to growth mainly in COVID-related products in US and Canada markets.

Sales	(YOY 89.6B JPY) 85.9B JPY	(-) Domestic sales YOY 95.9% (+) US sales YOY 117.4%
Core operating profit	(YOY 1.3B JPY) - 8.7B JPY	(-) Drop in gross profit margin due to the drug price revision (Price reduction rate: - 10.7%) (-) Delayed release of profitable products by Toyama Plan 1
Net Income attributable to parent	(YOY 0.1B JPY) - 145B JPY	

FY2022/3 Results by Segment

(Closing basis) (Million JPY)	Nichi-Iko Group				Sagent Group				Consolidated				Plan
	FY 2021/3	FY 2022/3	Gap	YOY	FY 2021/3	FY 2022/3	Gap	YOY	FY 2021/3	FY 2022/3	Gap	YOY	
Sales	72,326	65,615	-6,711	90.7%	17,304	20,316	+3,011	117.4%	89,631	85,931	-3,699	95.9%	195,000
COGS	59,802	67,997	+8,195	113.7%	14,148	17,082	+2,934	120.7%	73,950	85,079	+11,129	115.0%	-
Gross Profit	12,523	-2,382	-14,906	-19.0%	3,156	3,234	+77	102.5%	15,680	851	-14,829	5.4%	-
SG&A	9,708	10,257	+548	105.7%	3,366	3,226	-139	95.8%	13,074	13,483	+409	103.1%	-
R&D Expense	1,001	1,154	+152	115.3%	877	665	-212	75.8%	1,879	1,819	-60	96.8%	-
Other Income	144	746	+602	518.1%	-1	4	+6	-	142	751	+608	528.9%	-
Other Expense	345	327	-18	94.8%	0	0	+0	-	346	327	-19	94.5%	-
Operating Profit	1,612	-13,374	-14,986	-	-1,088	-652	+435	59.9%	523	-14,026	-14,550	-	500
Core Operating Profit	2,449	-8,137	-10,586	-	-1,088	-652	+435	59.9%	1,360	-8,790	-10,151	-	700

Capital Expenditure
8.3B JPY

(FY2021/3 2Q Actual **3.9B** JPY)

R&D Investment
6.6B JPY

(FY2021/3 2Q Actual **6.7B** JPY)

Depreciation
6.1B JPY

(FY2021/3 2Q Actual **6.3** JPY)

Additional reduction of directors' remuneration (from Nov. 2021)

Since Jul. 2021, the directors' remunerations have been reduced,
but further cut from the current monthly salaries for directors will be as follows.

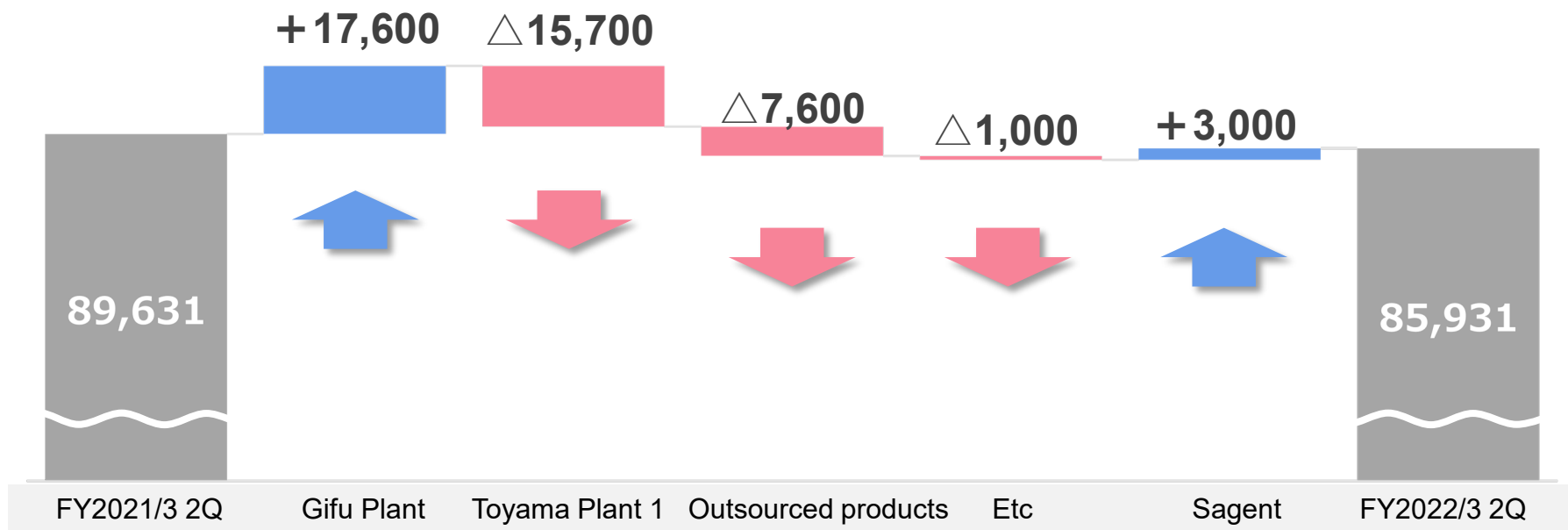
President & CEO: cut by 30% / Full-time directors: cut by 20% / Senior vice presidents: cut by 10%

Copyright 2021-2022 Nichi-Iko Pharmaceutical Co., Ltd.

Sales Change Factors and Analysis (IFRS)

Gifu Plant product sales (approx. 17.6B JPY) offset Toyama Plant 1 reduction in sales (approx. 15.7B JPY) caused by delayed production and product release. Other major factors: Decline in sales caused by termination of products supplied by other companies (approx. 7.6B JPY), and increase in sales by Sagent (approx. 3.0B JPY). In total, the sales declined by approx. 3.7B JPY (Total sales YOY: - 4.1%).

(Million JPY)



Summary of One-off Factors

FY2021/3 Q2

	FY2021/3 Q2 Closing base	
Sales	89,631	Voluntary recall (187)
COGS	73,950	Voluntary recall (157)
Gross Profit	15,680	
<i>GP margin</i>	17.5%	
SG&A	13,074	Voluntary recall (403) Gifu Plant merger expense (90)
R&D Expense	1,879	
Other Income	142	
Other Expense	346	
Operating Income	523	
<i>Operating margin</i>	0.6%	
(Core Operating Income)	(1,365)	

FY2022/3 Q2 (Million JPY)

	FY2022/3 Q2 Closing base	
Sales	85,931	Voluntary recall (- 1)
COGS	85,079	Voluntary recall (27) Reserve for obsolete DS etc. inventory* (4,838)
Gross Profit	851	
<i>GP margin</i>	1.0%	
SG&A	13,483	Voluntary recall (135) Gifu Plant merger expense (25)
R&D Expense	1,819	
Other Income	751	
Other Expense	327	Nichi-Iko R&D impairment (212)
Operating Income	-14,026	
<i>Operating margin</i>	-16.3%	
(Core Operating Income)	(-8,790)	

*Reserve for obsolete DS etc. inventory:

Allowance for inventory of DS etc. which may reach to its use-by date by the expected start of production or product release and may be disposed.

Capital and Business Alliance with Medipal HD Group



Business Alliance with Medipal HD Group to “Restore Trust”



Strengthen production & quality control systems

Build planned production & QC systems
Production & tests, optimize to number of staff



Secure stable supply

Optimize logistics system
Reduce small & frequent deliveries



Improve sales & profits

Cut cost thru. efficient production
Optimize raw material & product inventories



Essential “Restore Trust”

- Stable supply of secured quality products
- Develop drugs in greatest need
- Rapid reaction to market demands

- Collect needs as a pharmaceutical company

Deliver high quality drugs to people

Promote Nichi-Iko’s effort Accelerate “Restore Trust”

- Collect needs as a wholesaler

**Medical
personnel
Patients**

**Planned
order**

**Planned
production**



MEDIPAL HOLDINGS CORPORATION

**Medipal HD Group’s
Prescription drug wholesaler**

Authorized Generic (AG)

After a review of JV agreement etc. with Sanofi and license agreement with LTL Pharma, it is agreed that Nichi-Iko takes over marketing authorization of the following products in Japan after Dec. 1, 2021.

Also, we agreed to dissolve Nichi-Iko Sanofi-Aventis Co., Ltd., the JV company with Nichi-Iko and Sanofi as of Dec. 31, 2021.

Due to this dissolution, Nichi-Iko's AG product line-up expands to 6 products including Limaprost and Solifenacin.



**Fexofenadine hydrochloride
Tablets**
30mg/60mg



**PusoFeki Combination
Tablets**



Solifenacin Succinate Tablets
2.5mg/5mg

To be launched
in Dec. 2021

**AG products which marketing authorization
are taken over from Nichi-Iko Sanofi-Aventis**



Clopidogrel Tablets
25mg/75mg



**LoreAce
Combination
Tablets**



Limaprost Alfadex Tablets
5µg

Launch schedule of the Products Listed in Dec.

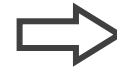
Product Name	Original Drug	Classification by efficacy	Approval Timing
SOLIFENACIN SUCCINATE Tablets 2.5mg / 5mg “Nichiiko”	Vesicare Tablets	Overactive bladder treatment	Feb. 15, 2021
SOLIFENACIN SUCCINATE OD Tablets 2.5mg / 5mg “Nichiiko”	Vesicare OD Tablets	Overactive bladder treatment	Feb. 15, 2021
ESZOPICLONE Tablets 1mg / 2mg / 3mg “Nichiiko”	Lunesta Tablets	Insomnia treatment	Feb. 15, 2021
DULOXETINE Capsules 20mg / 30mg “Nichiiko G”	Cymbalta Capsules	Serotonin noradrenaline reuptake inhibitor	Feb. 15, 2021
Palonosetron i.v. injection 0.75mg / 2mg “Nichiiko”	Aloxi i.v. injection	5-HT3 receptor antagonist anti-emetic	Feb. 15, 2021
Pemetrexed for I. V. infusion 100mg / 500mg “Nichiiko G”	Alimta for injection	Anti-metabolic anti-neoplastic	Feb. 15, 2021
ZILMLO Combination OD Tablets LD / HD “Nichiiko”	ZACRAS Combination Tablets	Long-acting AT1 receptor blocker / Long-acting CCB combination drug	Aug. 16, 2021
LEVETIRACETAM Tablets 250mg / 500mg “Nichiiko”	E Keppra Tablets	Anti-epilepsy	Aug. 16, 2021
LEVETIRACETAM Dry Syrup 50% “Nichiiko”	E Keppra Dry syrup	Anti-epilepsy	Aug. 16, 2021

Plan to launch 7 brands & 17 presentations in Dec. 2021

Biosimilar Pipeline and Development Status

Bevacizumab BS (Japan)

In 2020: Using overseas data,
Applied to PMDA in Nov. 2020



In 2022:
Expected to launch

Main target disease

Colon cancer

Domestic market size

95.0B JPY

Number of BS
entries

2 companies

Infliximab BS (USA)

In 2020: Completed Phase III
Obtained interchangeability data



In 2023:
Expected to be filed with FDA

Clinical trials

USA

Completed

Secured inter-
changeability data

Drug substance

Korea
Aprogen
Osong Plant



FDA accreditation

In progress

Formulation

USA
Sagent
Raleigh Plant



Tech. transfer

In progress

Filing

USA
Sagent



FDA filing

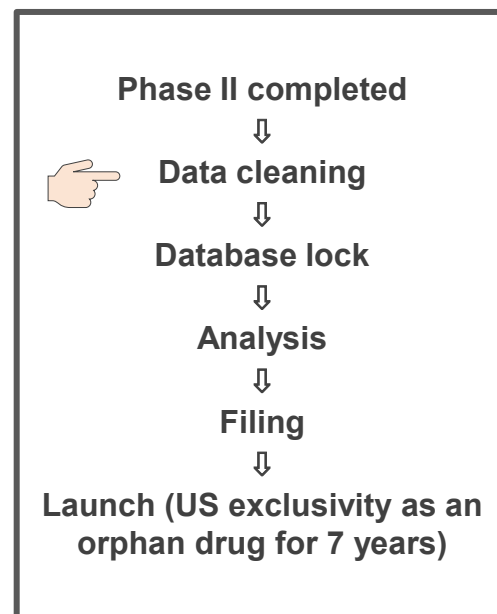
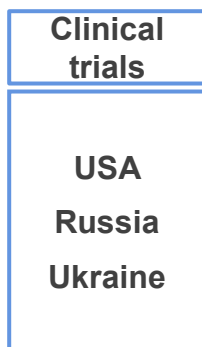
**Expected
in 2023**

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

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

Phase II

- ◆ Ingredient: Camostat mesilate (for rare disease)
- ◆ Total patient enrollment (target): 260
- ◆ Patient enrollment (plan): USA130 / Eastern Europe 130
- ◆ Scheduled filing: H1 2022
- ◆ Designated as a fast-track drug



Nichi-Iko Group SDGs Declaration

Based on our understanding that “sustainability” is indispensable to long-term improvement of our company value, Nichi-Iko Group is going to promote SDGs with the following 12 targets and do our best to “Achieve a Healthy and Meaningful Society” as a pharmaceutical company, together with our on-going activities for “Environment, Society and Governance (ESG)” through our main business.



Aug. 17, 2021
Nichi-Iko
Pharmaceutical Co., Ltd.
Yuichi Tamura

FY2022/3 Full Year Forecast

◆ Reflecting the financial results of domestic and overseas businesses,
and the most updated status of production and product release at Toyama Plant 1,
as well as inventory appraisal loss

FY2022/3 Full Year Forecast (Consolidated)

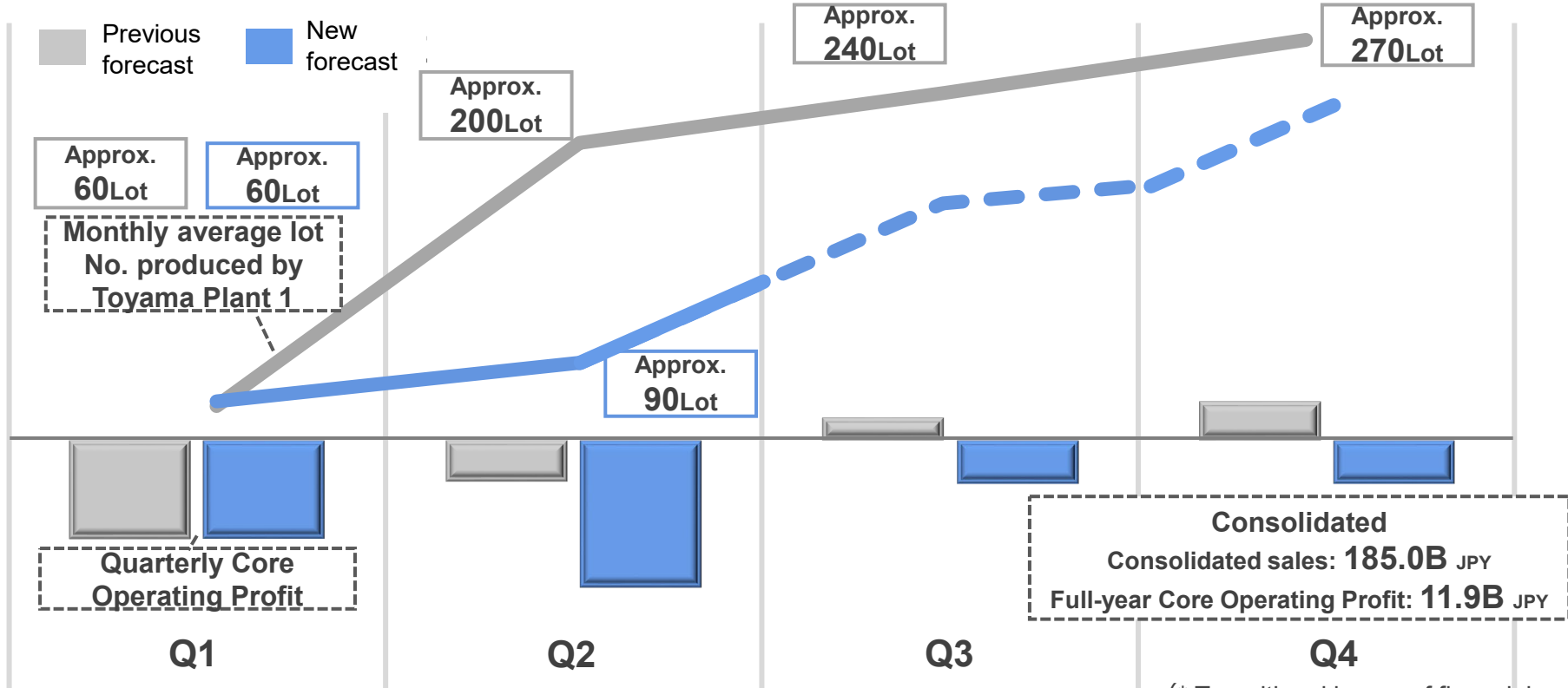
(Unit: Billion JPY)	1H (Actual)	2H (Revised on Nov. 11)	Full-year (Revised on Nov. 11)	Full-year (Revised in May)
Sales	85.9B	99.0B	185.0B	195.0B
Core Operating Profit	- 8.7B	- 3.1B	- 11.9b	0.7B
Operating Profit	- 14.0B	- 3.0B	- 17.1B	0.5B
Net Income attributable to parent	- 14.5B	- 4.0B	18.6B	0.2B

To achieve the full-year forecast

“Resume production and product release at Toyama Plant 1”
 “Sales contribution by AG products, newly listed products & Gifu Plant”
 “Gifu Plant’s products offset reduction in products from Toyama Plant 1”
 “Improve profit by strict management of cost in logistics and other expenses.”

* The above-mentioned forecasts are based on the information available as of the date when this information is disclosed. Actual performance may differ materially from the forecasts due to a variety of factors.

FY2022/3 Full Year Forecast (Domestic) and Lot No. by Toyama Plant 1



The gap between the previous forecast and the revised forecast

No. of lots to be produced: Risk assessment for all products has been completed, but formulation improvement and production adjustment is taking longer time than expected.

Core Operating Profit: Production and product release of profitable products are delayed.

Rapidly switch to Gifu Plant products and Elmed's products, if any replacements are available.
We are conducting a review of all products, with an emphasis of maintaining profitability and stable supply to the market.

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.

The company and any other information sources for this document bear no responsibility for damages or losses resulting from the use of this information.