



# FY 2020/3 H1 Presentation

**November, 2019**

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

**President & CEO**

**Yuichi Tamura**



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

TSE : 4541

# FY2020/3 H1 Financial Summary

**Q2 consolidated results increased in sales & profit:**  
**Nichi-Iko increased in sales & profit due to Elmed contribution, etc.**  
**(The highest sales ever)**  
**Sagent decreased in sales & profit due to India supply issue**

<b>Sales</b>	(FY 2019/3 H1 82.3 B JPY) <b>91.5 B JPY</b>	(+) Domestic Generic Sales(YoY) 122.1% (-) US market Sales Growth(YoY) 79.3%
<b>Core Operating Profit</b>	(FY 2019/3 H1 4.9 B JPY) <b>3.9 B JPY</b>	(+) Improve along with Domestic Sales Growth (-) Temporary cost of NHI Drug Price Revision (-) US Supply Matter, In-house Production Investment
<b>Net Income</b>	(FY 2019/3 H1 4.6 B JPY) <b>3.0 B JPY</b>	(+) Gain on Sales of Aprogen Shares (-) Foreign Exchange Loss (USD/JPY) (-) Equity in Net Loss of Affiliated Company

average exchange rate				JPY/USD	year-end exchange rate				JPY/USD
FY 2018 Q1	109.07	FY 2019 Q1	109.90	budget rate 108.00	3/2018	106.24	3/2019	110.99	
FY 2018 Q1	111.46	FY 2019 Q2	107.35		9/2018	113.57	9/2019	107.92	

# FY2020/3 H1 Performance by Segment (YoY)

YoY

(Million JPY)	Nichi-Iko Group			Sagent Group			Consolidated		
	FY 2019/3 H1	FY 2020/3 H1	YoY	FY 2019/3 H1	FY 2020/3 H1	YoY	FY 2019/3 H1	FY 2020/3 H1	YoY
Sales	63,853	76,851	120.4%	18,493	14,668	79.3%	82,346	91,519	111.1%
COGS	50,009	61,170	122.3%	14,157	11,339	80.1%	64,166	72,509	113.0%
Gross Profit	13,843	15,680	113.3%	4,335	3,329	76.8%	18,179	19,009	104.6%
SG&A	8,474	9,858	116.3%	3,140	3,121	99.4%	11,615	12,980	111.8%
R&D expense	1,203	1,149	95.5%	711	951	133.8%	1,915	2,100	109.7%
Other expense	273	170	62.3%	0	-2	-	273	168	61.5%
Other Income	90	318	353.3%	111	0	-	202	318	-
Core Operating Profit	4,455	4,664	104.7%	483	-747	-	4,939	3,917	79.3%
Operating Profit	4,348	4,524	104.0%	372	-747	-	4,720	3,777	80.0%

# FY2020/3 H1 Performance by Segment (vs plan)

## vs Plan

(Million JPY)	Nichi-Iko Group			Sagent Group			Consolidated		
	Plan	Actual	%	Plan	Actual	%	Plan	Actual	%
Sales	81,000	76,851	94.9%	17,000	14,668	86.3%	98,000	91,519	93.4%
COGS	65,400	61,170	94%	13,000	11,339	87.2%	78,400	72,509	92.5%
Gross Profit	15,600	15,680	101%	4,000	3,329	83.2%	19,600	19,009	97.0%
Gross Profit Ratio	19.3%	20.4%		23.5%	22.7%		20.0%	20.8%	
Core Operating Profit	3,000	4,664	155%	100	-747	-	3,100	3,917	126.4%
Core Operating Profit Ratio	3.7%	6.1%		0.6%	-5.1%		3.2%	4.3%	
Operating Profit	3,000	4,524	151%	100	-747	-	3,100	3,777	121.8%
Operating Profit Ratio	3.7%	5.9%		0.6%	-5.1%		3.2%	4.1%	

Interim Dividend  
(Planned)

**15.0 JPY**

Capital Expenditure

**4.5 B JPY**

(FY/2019 H1 2.2 B JPY)

R&D Investment

**7.3 B JPY**

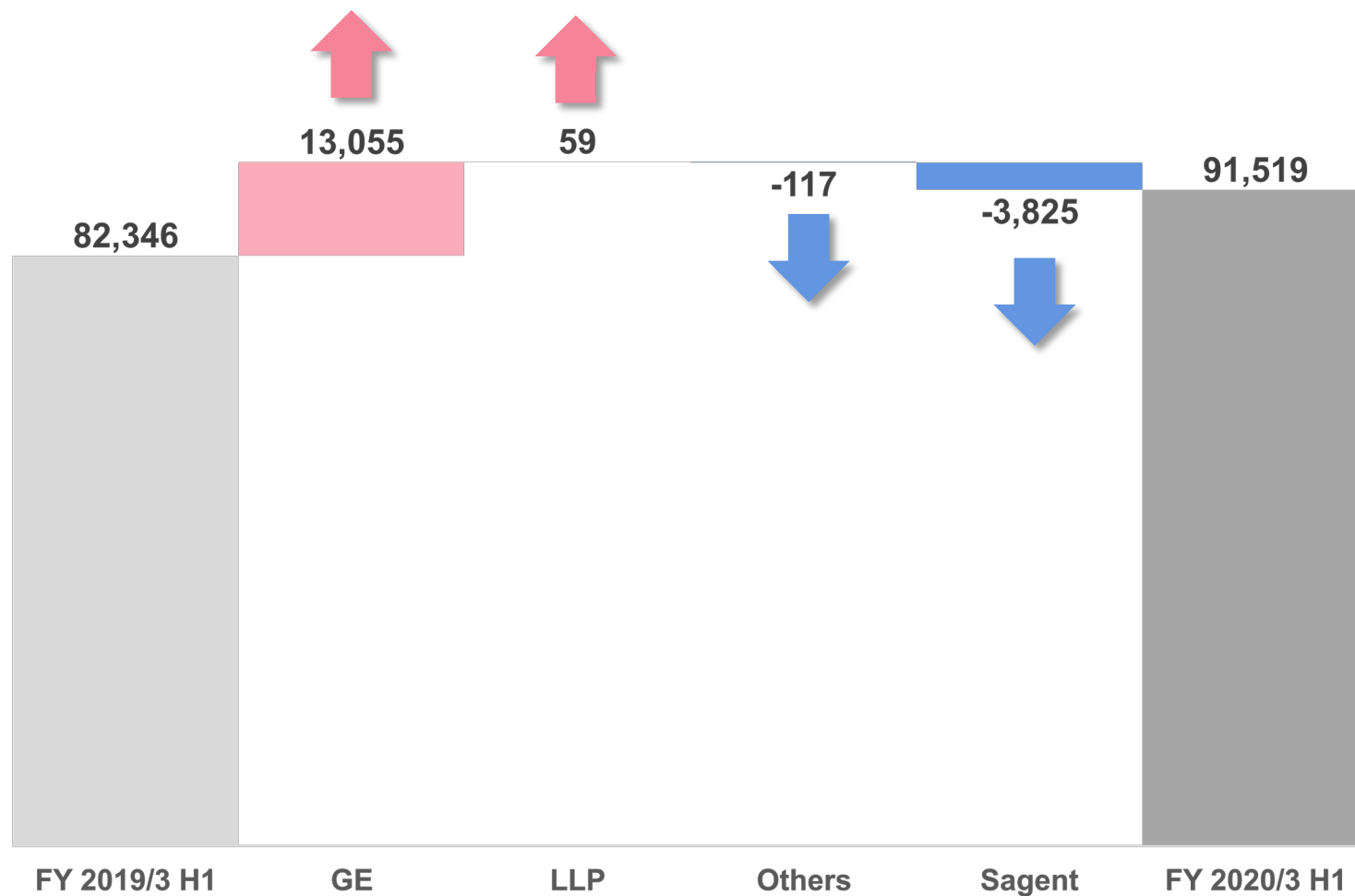
(FY/2019 H1 5.1 B JPY)

Depreciation

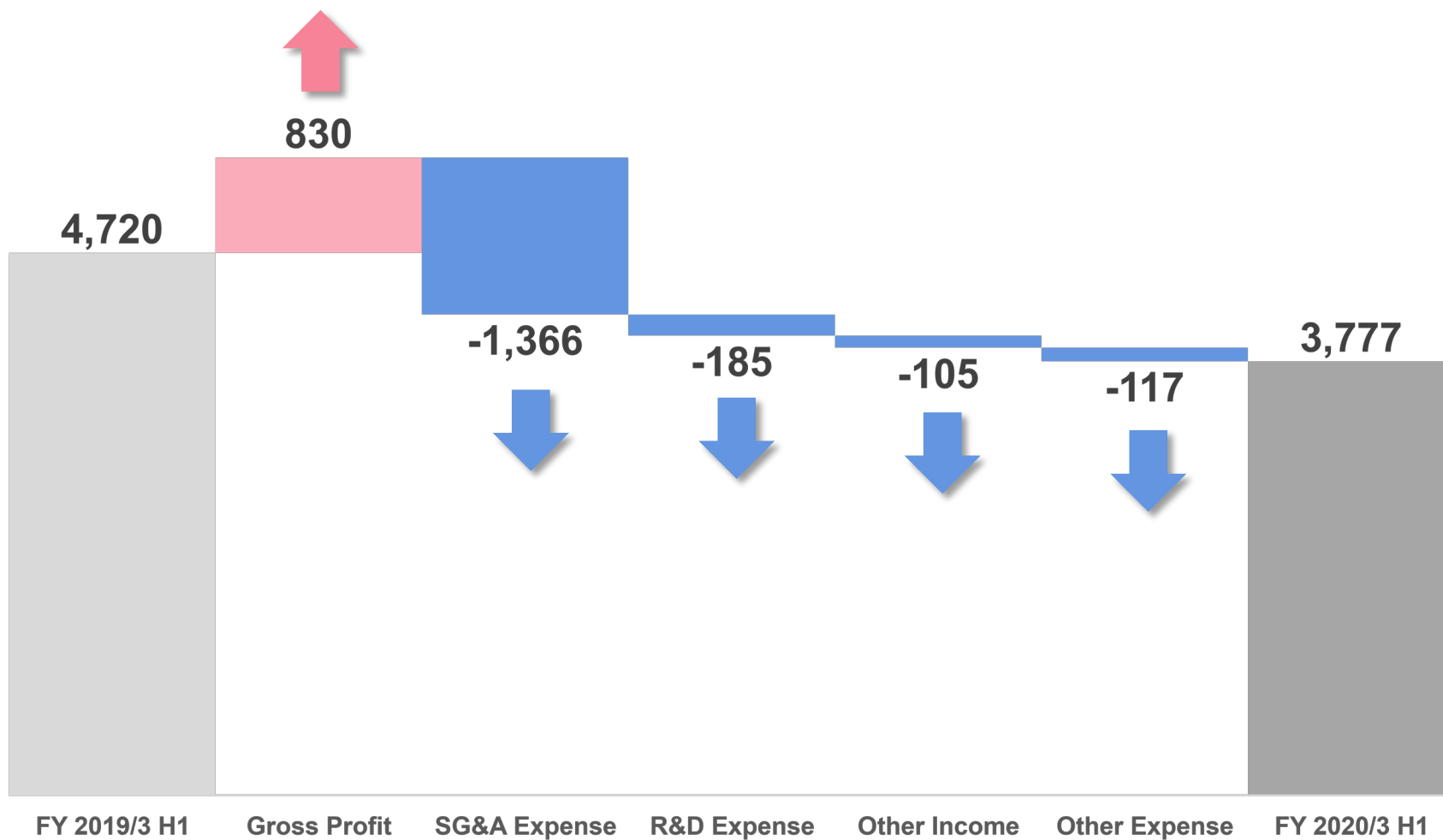
**5.4 B JPY**

(FY/2019 H1 4.6 B JPY)

# Sales Change Factors & Analysis (IFRS)



# Operating Profit Change Factors & Analysis (IFRS)



## 1 Issues

**May 2019**  
**Supplier A (India)**  
**received Form 483\***  
**from FDA**

**Oct 2019**  
**Supplier B (India)**  
**received Form 483\***  
**from FDA**

**\*Form483**

Document issued by FDA when investigators observed conditions that in their judgement may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

**13 products (CMP and pipeline) affected**

## 2 Actions Taken

**Accelerated transfer of production to FDA-approved sites**

- In-house (10)
- Other COMs (3)

**Sagent Raleigh Site**



**Omega Montreal Site**



## 3 Future Benefits

**Stable product supply**

**Increased ability to serve US market**

**Improved gross profit by in-house production**

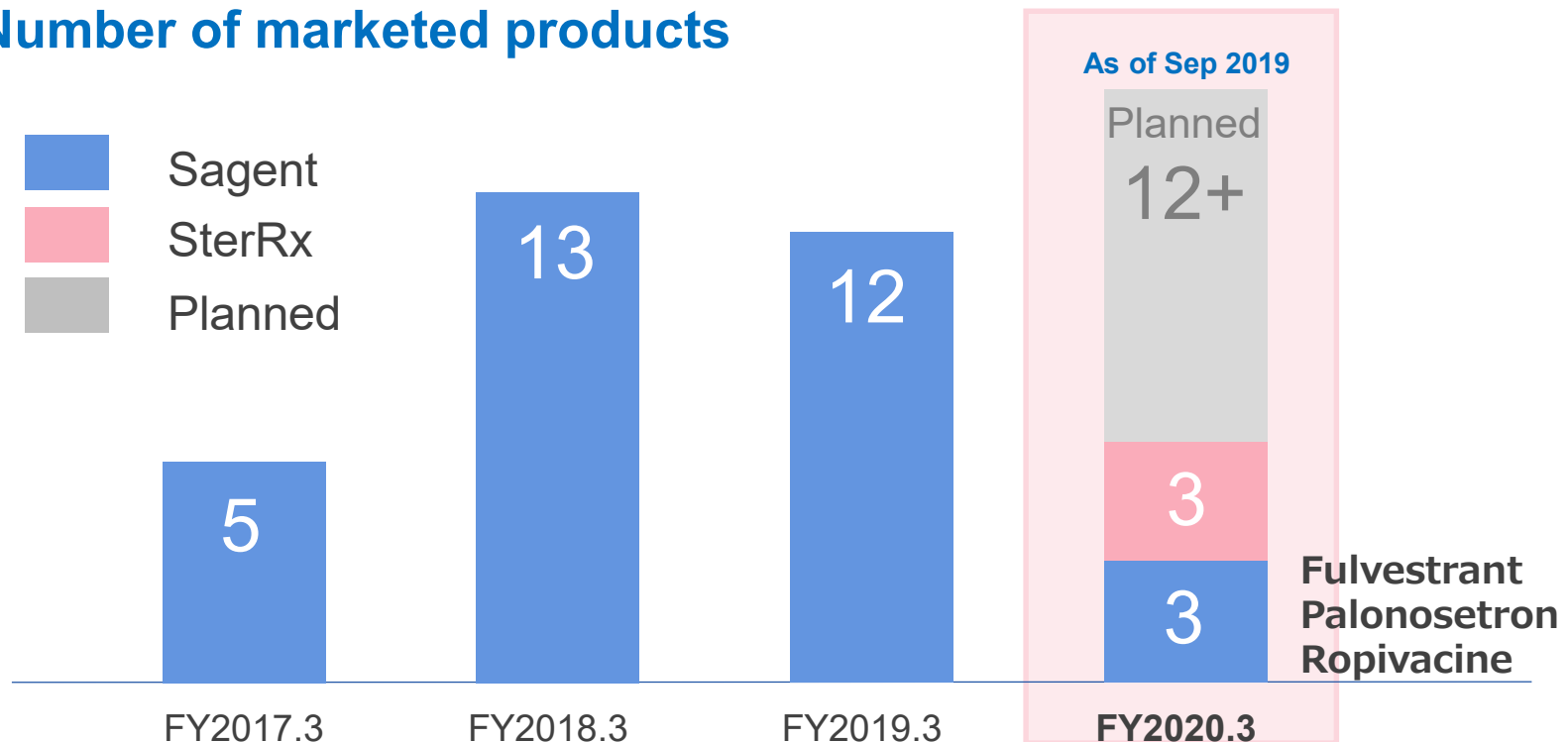
## Sagent successfully launched Fulvestrant at market formation

- ✓ Launched 3 products in H1 and expect additional 3-5 new products in H2

## SterRX constantly expanding new product line-up

- ✓ Launched 3 products in H1 and expect additional 3-5 new products in H2

### Number of marketed products





## Latest Update: Etanercept BS “Nichi-Iko” to be launched in Nov, 2019

Product	Market	Pre-Clinical	Phase I	Phase III	Filing/Approval
Etanercept	Japan	Plan to launch in Nov.2019			
Infliximab	US	Phase III done, mid of data analysis			
Trastuzumab	Japan/US/EU	Phase I			

## Revised financial outlook based on H1 results

(Million JPY)	Previous Forecast			Revised Forecast			Variance
	Nichi-Iko Group	Sagent Group	Consolidated	Nichi-Iko Group	Sagent Group	Consolidated	Consolidated
<b>Sales</b>	164,400	36,600	<b>201,000</b>	160,000	34,000	<b>194,000</b>	<b>Δ7,000</b>
<b>COGS</b>	132,600	27,900	<b>160,500</b>	128,100	27,900	<b>156,000</b>	<b>Δ4,500</b>
<b>Gross Profit</b>	31,800	8,700	<b>40,500</b>	30,800	8,200	<b>39,000</b>	<b>Δ1,500</b>
Gross Profit Ratio	19.3%	23.8%	20.1%	19.3%	24.1%	20.1%	
<b>Operating Profit</b>	8,300	200	<b>8,500</b>	8,500	0	<b>8,500</b>	<b>-</b>
Operating Profit Ratio	5.0%	0.5%	4.2%	5.3%	0.0%	4.4%	
<b>Net Income</b>	6,900	100	<b>7,000</b>	6,000	0	<b>6,000</b>	<b>Δ1,000</b>
Net Income Ratio	4.2%	0.3%	3.5%	3.8%	0.0%	3.1%	

**Annual Dividend  
(Planned)**

**30.0 JPY**

**Capital Expenditure**

**9.0 B JPY**

(FY/2019 H1 5.0 B JPY)

**R&D Investment**

**10.5 B JPY**

(FY/2019 H1 10.8 B JPY)

**Depreciation**

**7.6 B JPY**

(FY/2019 H1 9.4 B JPY)



# Cefazolin Sodium Injection “Nichi-Iko”

Supply resumption  
and  
recurrence preventive actions

**Supply resumed on Nov 25, 2019  
(back to normal shipment from Jan 2020)**

## For securing stable supply

### 4 issues must be solved

- 1 Starting substance**  
(mono-source)
- 2 API**  
(contamination)
- 3 Production Facility**  
(single site, mono-source)
- 4 Profitability**

Pluralize

### Current Status & Actions Taken

- 1 TAA supplier (China) only**
- 2 Considering to add 2<sup>nd</sup> TAA supplier**
- 1 Company A (Italy) – on problem-solving**
- 2 Company B (Italy)**
- 3 Considering to add 3<sup>rd</sup> API supplier**
- 1 Production outsourced overseas**
- 2 Investing in Shizuoka Plant for capability enhancement and multi-API: New facility to launch in Oct, 2020**
- Requesting for review of unprofitable products**  
[For April 2020 NHI Drug Price Revision](#)



# Ranitidine Tablets “Nichi-Iko” Voluntary Recall

# Ranitidine Tablets “Nichi-Iko” Voluntary Recall



2019 年 10 月 2 日

各 位

## ラニチジン錠「日医工」自主回収のお知らせ

日医工株式会社（本社：富山県、代表取締役社長 田村友一、以下「当社」）は、ラニチジン錠「日医工」（以下、「本剤」）を本日 10 月 2 日より自主回収することといたしましたので、お知らせいたします。

海外において原薬ラニチジン塩酸塩を使用した製剤から発がん性物質である N-ニトロソジメチルアミン（以下、「NDMA」）が検出されたとの報告を受け、当局からの指示で本剤の出荷を停止し、現在、本剤及び本剤に使用しております原薬ラニチジン塩酸塩について NDMA 混入の有無を分析しております。

現在のところ本剤による重篤な健康被害等に関する報告は受けておらず、当社の原薬は今回の報告にあったものとは異なりますが、現時点では NDMA の混入の可能性について否定することができないため、予防的な措置として自主回収することといたしました。今後の製品出荷については改めてご案内いたします。

また本剤においては、安定供給の目的から原薬複数化によりセカンドソースを保有しておりましたが、海外の報告にあった同メーカーの原薬であったことから使用しておりません。同メーカーの原薬を使用した本剤の市場在庫はございません。

当社は、健康・生命に関わる製薬企業として、今後も患者様とそのご家族、そして医療関係者の方々に「超品質」をお届けするための取り組みを続けてまいります。

以 上

問い合わせ先		
患者様、一般のお客様	医療関係者様	報道関係者様
0120-039-215	0120-517-215	076-442-7026

問い合わせ先  
日医工株式会社 社長室 コーポレート・コミュニケーション部  
TEL 076-442-7026

1

## Voluntary Recall

The possibility of N-nitrosodimethylamine (NDMA) contaminated in our China API is undeniable

→ **Precautionary Recall**

2

## Multiple API sources

- ☑ **Ranitidine API sourced from China & India (disclosed information on our website)**
- ☑ **No longer use India API produced by the manufacturer reportedly causing the NDMA contamination issue**

3

## Premium Quality-based mindset

# The 8<sup>th</sup> Mid-term Management Plan Update



**1** Continue our deeper pursuit of business arenas (where to play)

**2** Relentless efforts for operational excellence

**3** Drive for global standard of quality and competitive edge

**4** Be the most trusted life science company driven by our ESG activities

- **Strategic Alliance with MedPeer**
- **Progress of co-promotion with Eisai**
- **PMP 8 and further optimization of operations**
- **Cost synergy driven by integration of Elmed**
- **Entrance into Chinese generic drugs market**
- **Practical use of LNG**
- **Contribution to local healthcare communities**

## New Generic Drugs Business Model

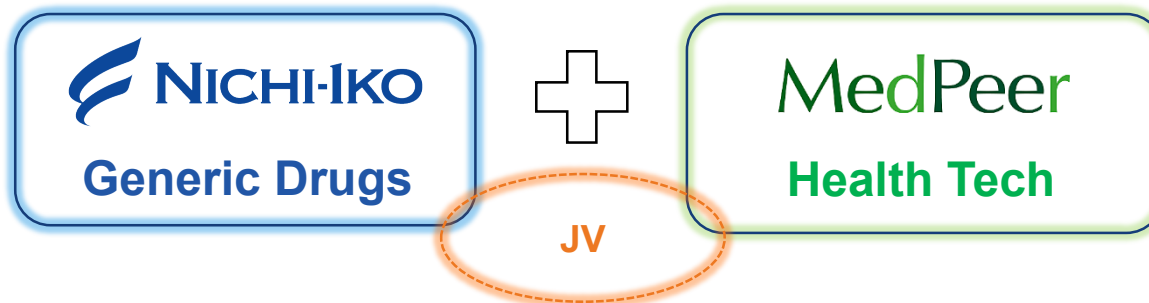
“Family” dispensing  
pharmacy support

Gx Digital Marketing

Gx Development  
Scheme

Joint business rollout using kakari APP   Marketing aligned with community site   Collaborative development with MD

- ✓ Nichi-Iko and MedPeer tie up to deepen and evolve our business fields in ever-transforming generic drugs industry
- ✓ We aim to create a new Gx business model to connect with our patients and their families responding to their behavior changes
- ✓ We are considering to launch a joint venture for collaborative business rollout



### Medpeer Company Profile

President & CEO: Dr. Yo Iwami

Foundation: December, 2004

Expertise: Dedicated community site for doctors, other related businesses

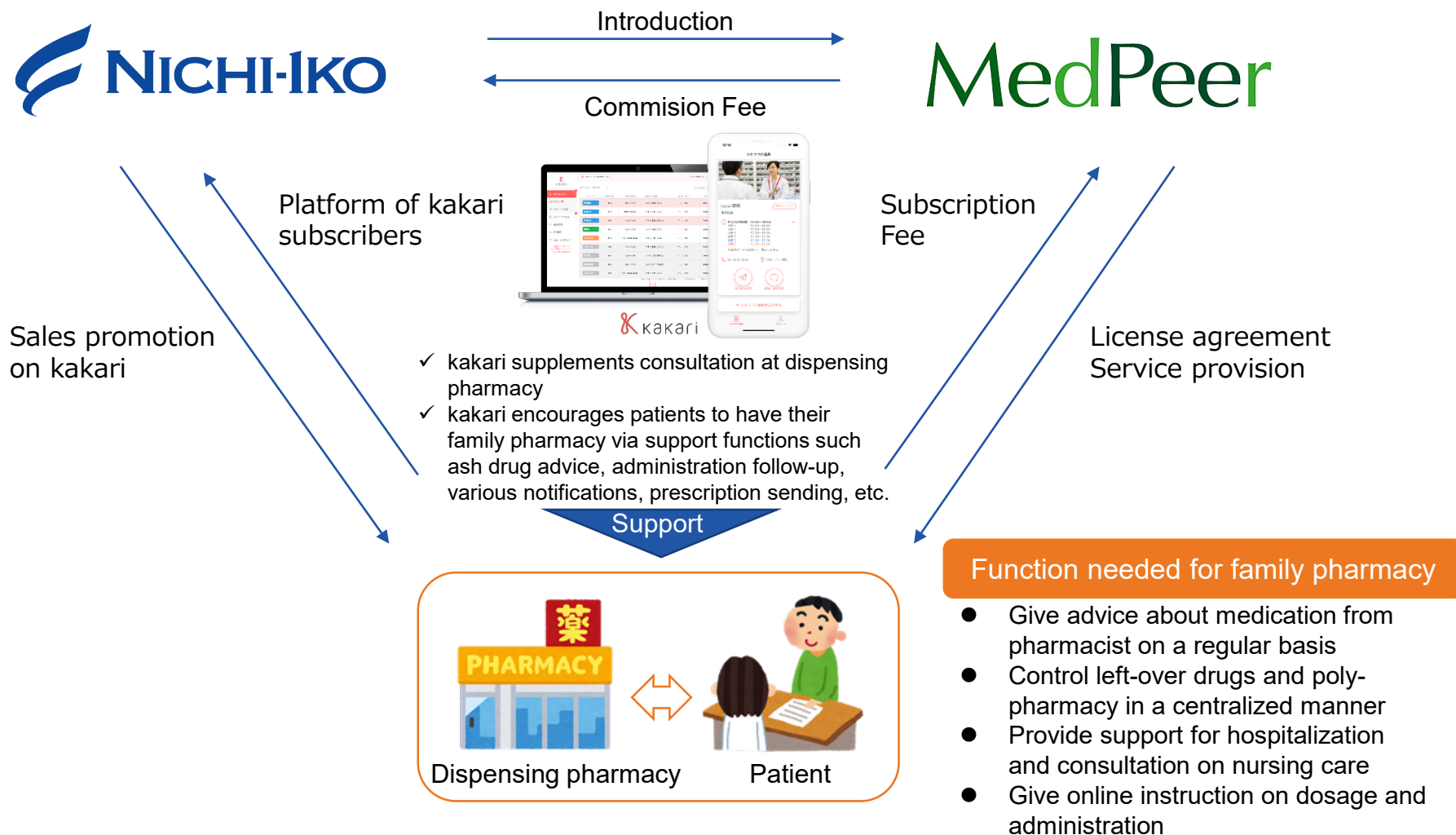
Listed Market: Tokyo Stock Exchange Mothers

Capital Stock: 1,065MM (JPY)



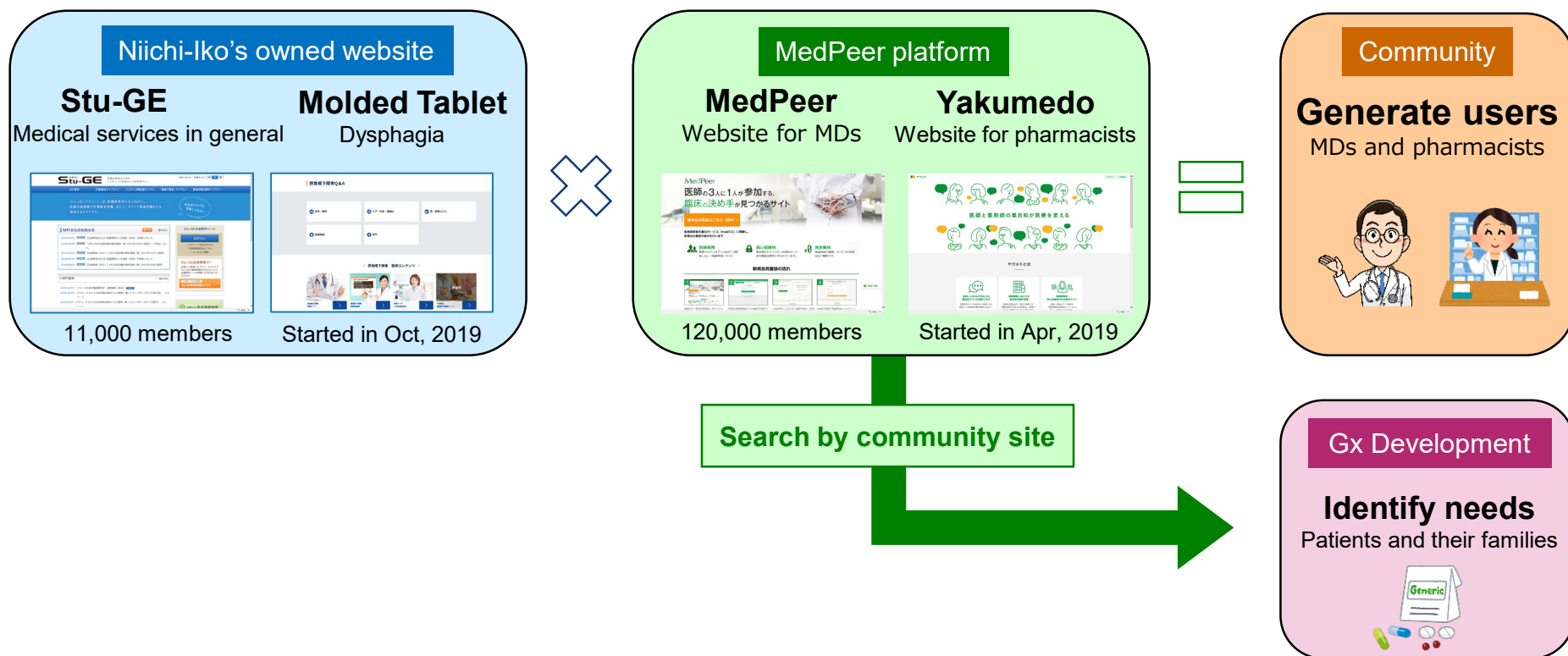
# Scheme of Strategic Alliance with MedPeer

- Phase I : Joint sales promotion using kakari, a mobile APP designed to support “home” dispensing pharmacy system
- Phase II : Roll out joint business on a platform of kakari APP subscribers



# Scheme of Strategic Alliance with MedPeer

- Execute a new Gx digital marketing in alignment with MedPeer Yakumedo, a community site designed and developed for MDs and pharmacists
- Improve efficiency of sales rep activities through multi channel promotion and develop a path to access new MDs and pharmacists



- Build a new drug development scheme to identify patients and their families' unmet needs through the community site and develop the formulations

# Progress of Eisai Co-promotion



**Co-promotion with Eisai started on Apr 1, 2019**

Remedial Effect	Product Name
Antitumor drug	Capecitabine Tablets
Antitumor drug	Gefitinib Tablets
Antitumor drug	Docetaxel for Infusion
Antiviral chemotherapy drug	Entecavir Tablets

High trust of Eisai

Approach to  
oncology pharmacists

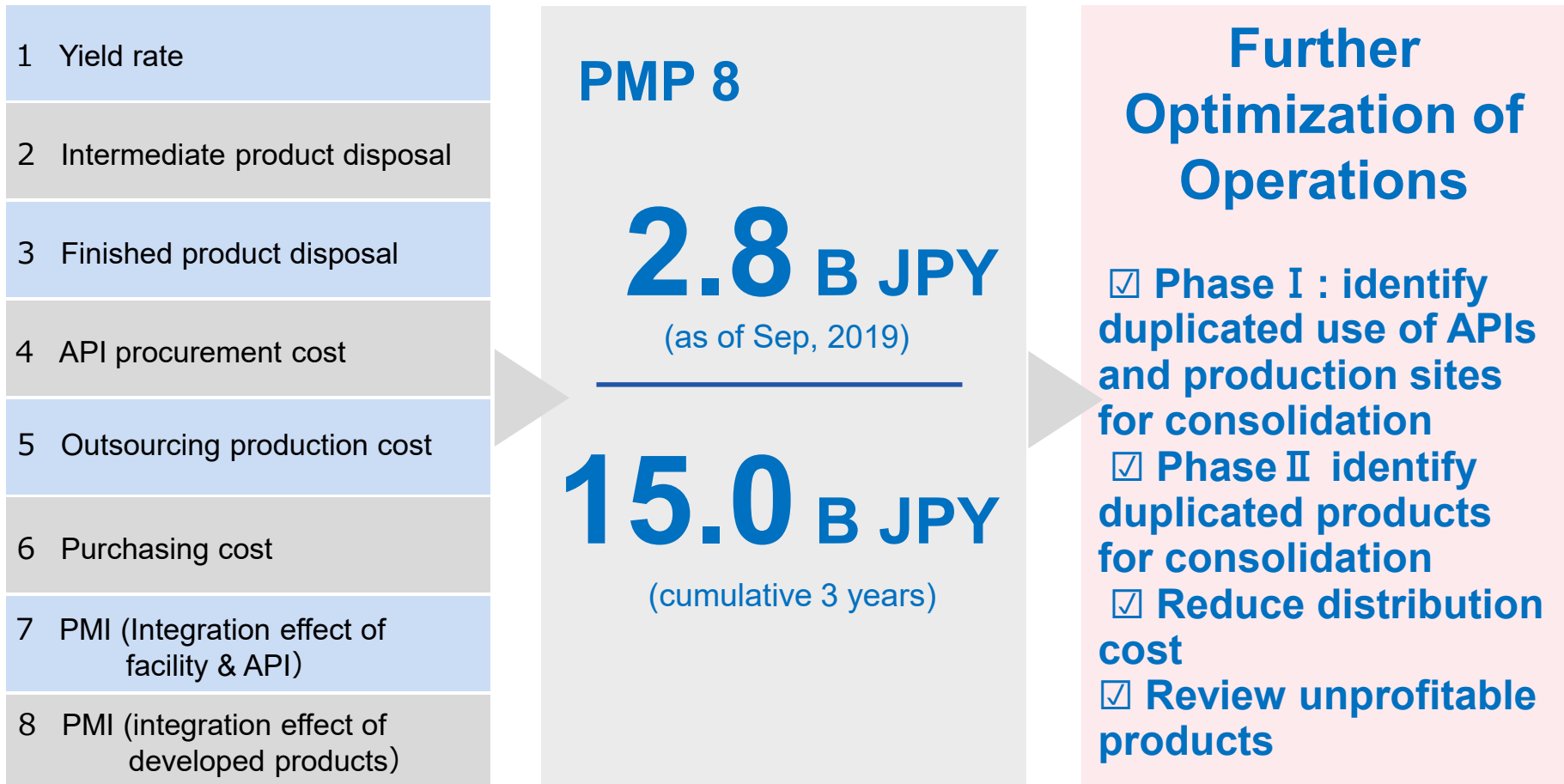
Backup from Eisai

Regular customer calls by  
both side of sales reps

Collaborative effort in product  
sales with hospitals

**Use co-promotion with Eisai as a trigger to enter into new arena**

Expect to reduce the cost by 15B JPY+ over the next 3 years through FY2022/3 – progress status on track



## Chinese Pharmaceutical Market

- ✓ the second largest market in the world after US market
- ✓ generic drugs account for more than 70% of its market in terms of value

## Pharmaceutical Business Growth

- ✓ Due to the rapid aging and the government's policies to promote the generic drug market, the continuous growth of generic drugs is predicted

## Issue of Generic Drugs in Chinese Pharmaceutical Market

- ✓ To improve the quality of generic drugs, the Chinese government is establishing the stable supply system of high quality generic drugs equivalent to the original drugs, such as it introduces the generic quality consistency evaluation system and provides priority response to the government's centralized procurement system for the generic drugs which have passed its evaluation test.

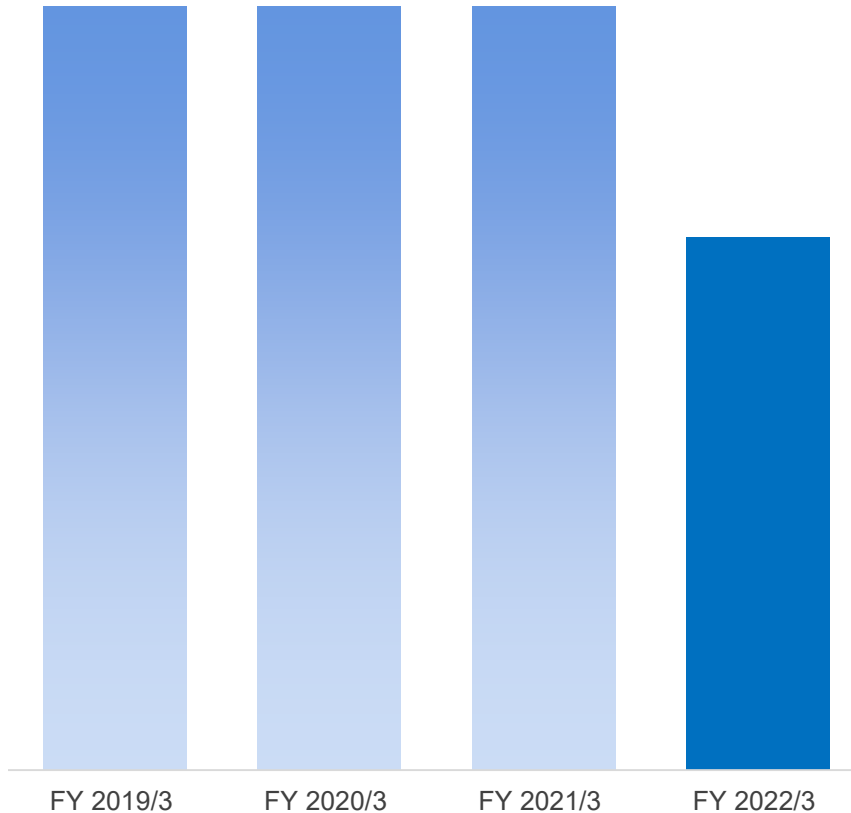
## Time Schedule

- ✓ Eisai and Nichi-Iko will select the first two products in this fiscal year, and subsequently prepare to launch one to two products every year for the continuous launch from FY2024.



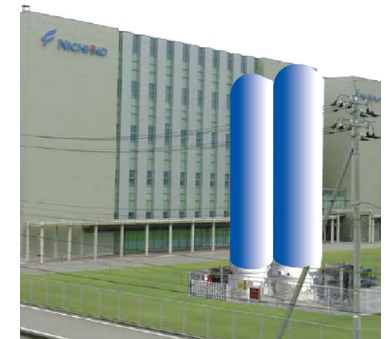
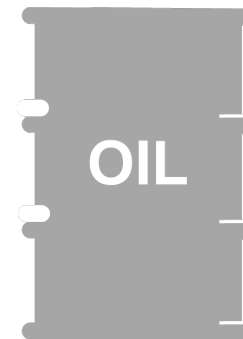
**Nichi-Iko prepares for new launches in China under the collaborative effort with Eisai by leveraging Eisai's business foundation in the country**

CO<sub>2</sub> Emission



**30% reduce**

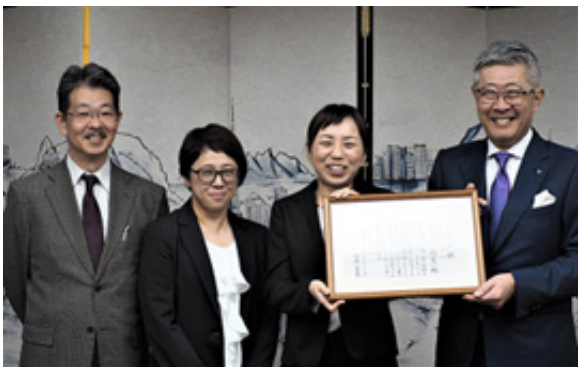
Toyama Plant 1 (from previous year)



Nichi-Iko Group strives to solve social and regional issues though the initiatives only pharmaceutical company can take.

Donation for “Fukurou-no-kai”, a group of patients suffering from triple-negative breast cancer

Nichi-Iko donated Carboplatin Injection 450mg “Nichi-Iko” in support of Phase 3 Randomized Controlled Trial of Carboplatin in Triple Negative Breast Cancer Patient with Residual Invasive Carcinoma After Neoadjuvant Chemotherapy (Kobe University Hospital, General Surgery) in August, 2019



Certificate of appreciation

Gx advocacy activities  
Lecture session of sterilizing hands & fingers

Roll out localized activities to meet regional needs

- <Namerikawa-shi>
  - ✓ Integrated alignment
  - ✓ Infection prevention & Correct hand washing seminar
- <Matsudo-shi>
  - ✓ Integrated alignment for medical expense optimization
  - ✓ Special booth to advocate Gx use
- <Toyama-shi>
  - ✓ Integrated alignment for medical expense optimization
  - ✓ Donate infectious disease prevention disinfectant





# 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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