



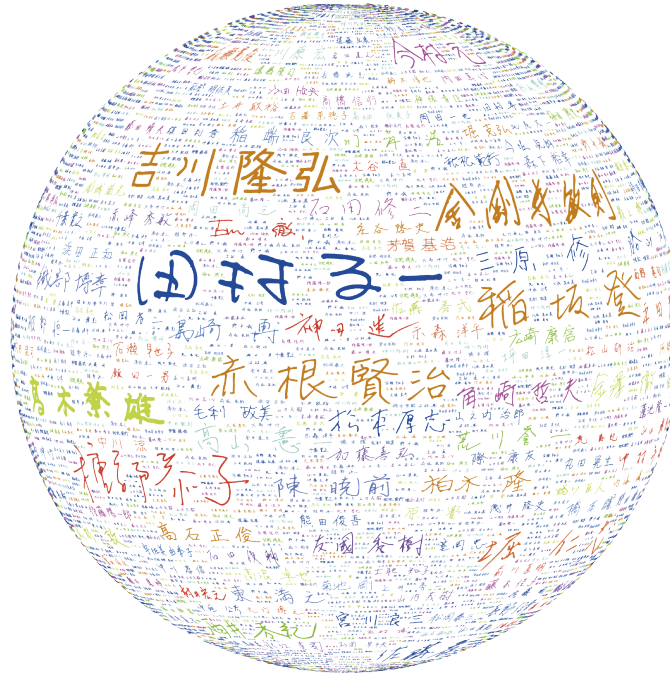
FY2021/3 H1 Presentation

November 2020

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

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

Create a system for trust and confidence



One Heart
One Vision
ONE NICHI-IKO

Pledge of Trust and Confidence

Quality Policy of Nichi-Iko Group

Each employee of Nichi-Iko Group shall comply with all the pharmaceutical laws and regulations in force. In order to live up to the trust and confidence expected of us by the patients and their families, pharmacists, doctors, wholesalers, as well as other pharmaceutical companies around the world, we pledge the following. With this pledge in place we shall act always as the most trusted generic pharmaceutical company devoted to best serve with compassion our patients around the world who suffer from illnesses by developing, manufacturing, distributing, and managing our products and operations in a most responsible manner.

<Quality Behavioral Principles>

1. We adhere thoroughly to laws and regulations in force with prime considerations given to the ethics and morals as a corporation engaged in healthcare services
2. We make relentless efforts to secure and improve our quality
3. We deliver safe and reliable pharmaceutical products which are based on the appropriate judgements enabled through transparent sharing of information.
4. We value sharing and succession of technology and skills, talent development and continuous efforts of education thereby enhancing on our high regard for quality
5. We shall play an integral part in the efforts to deliver our pharmaceutical products to the patients stably.

Based upon these 5 Behavioral Principles, every one of us is committed to strive earnestly to defend and nurture Nichi-Iko's quality endeavor, in order to deliver on customers' trust and confidence in us.

Lower sales and profits on a consolidated basis

Nichi-Iko Group decreased in sales and profits (impacted by drug price revisions in October 2019 and April 2020 as well as restriction of medical visits)

Sagent Group increased in sales but decreased in profits (sales up mainly due to the sales growth of COVID-19 related products)

Sales	(FY2020/3 91.5 B JPY) 89.6 B JPY	(-) Domestic sales YoY 94.1% (+) US sales YoY 118.0% (-) Overall decrease in volume due to reduction in medical examinations and postponement of operations
Core operating profit	(FY2020/3 3.9 B JPY) 1.3 B JPY	(+) Steady sales expansion of domestic listed products (-) Decrease in the gross profit margin due to the impacts of price revisions (rate of price reduction: Δ 10.7%) (-) Investment in plant operations in the U.S.
Net income	(FY2020/3 3.0 B JPY) 0.1 B JPY	(-) Recorded a gain on the sale of a portion of Aprogen's shares in the same period last year (1.8 B JPY)

Average exchange rate (PL)

					JPY/USD
FY2020/3 Q1	109.90	FY2021/3 Q1	107.62	Current budget rate	108.00
FY2020/3 Q2	107.35	FY2021/3 Q2	106.22		

Year-end exchange rate (BS)

				JPY/USD
Jun 2019	107.79	Jun 2020		107.74
Sep 2019	107.92	Sep 2020		105.80

FY2021/3 H1 Results by Segment

(Closing basis)

(Million JPY)	Nichi-Iko Group				Sagent Group				Consolidated			
	FY2020/3	FY2021/3	Variance	YoY	FY2020/3	FY2021/3	Variance	YoY	FY2020/3	FY2021/3	Variance	YoY
Sales	76,851	72,326	-4,525	94.1%	14,668	17,304	+2,636	118.0%	91,519	89,631	-1,888	97.9%
COGS	61,170	59,802	-1,368	97.8%	11,339	14,148	+2,808	124.8%	72,509	73,950	+1,440	102.0%
Gross Profit	15,680	12,523	-3,156	79.9%	3,329	3,156	-172	94.8%	19,009	15,680	-3,329	82.5%
SG&A	9,858	9,708	-150	98.5%	3,121	3,366	+244	107.9%	12,980	13,074	+93	100.7%
R&D expense	1,149	1,001	-147	87.1%	951	877	-73	92.2%	2,100	1,879	-221	89.5%
Other income	170	144	-26	84.7%	-2	-1	+1	50.0%	168	142	-25	84.5%
Other expenses	318	345	+26	108.5%	0	0	+0	-	318	346	+27	108.8%
Core Operating Profit	4,664	2,449	-2,214	52.5%	-747	-1,088	-341	145.6%	3,917	1,360	-2,556	34.7%
Operating Profit	4,524	1,612	-2,912	35.6%	-747	-1,088	-341	-	3,777	523	-3,254	13.8%

Interim dividend
(planned)

15.0 JPY

Capital expenditures

3.9 B JPY

(FY2020/3 4.5 B JPY)

R&D investment

6.7 B JPY

(FY2020/3 7.3 B JPY)

Depreciation

6.3 B JPY

(FY2020/3 5.4 JPY)

1

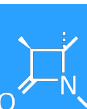
Optimization of the group's production system through promoting in-house production, etc.

Consolidation of APIs, review of overlapping products (Nichi-Iko, Elmed and Takeda Teva), and rationalization of production systems. Improving the gross profit margin through in-house manufacturing of specialty drugs.



Leveraging the specialty formulation line
(Promotion of CMO business)

Improving gross profit margin by in-house production



Consolidation of overlapping products

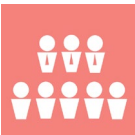
Rationalization of production systems of overall Nichi-Iko Group

Optimization of products manufactured by group plants

2

Enhancement of the quality control system

Acquisition of Takeda Teva's global quality control system, excellent human resources and know-how. Quality management system with 600 employees, external know-how gained from CMO business.



Quality control personnel

Global quality standards

CMO business

New quality policy

Strengthening the quality control system

Incorporating a quality culture that relies on global quality standards

Main Action

- Establish the Nichi-Iko Gifu Plant Integration Promotion Office
- Understand the current status of the organization and operations
- Build a cooperative structure for development and quality control
- Select priority duplicated products for integration
- Identify capital investment to accelerate in-house production
- Simulation for group production optimization

Priority Issues

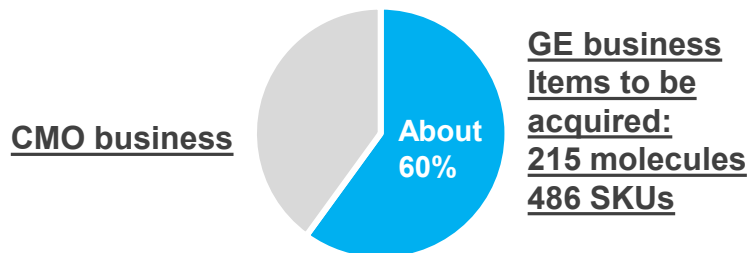
Comencement of promotion of Takeda Teva products and its acquisition

NEXUS
Better than the Best.



For products that will be acquired beginning on February 1, 2021:

- All product promotions will be conducted by Nichi-Iko, while and Marketing Authorizations will transfer in stages



Sales of the acquired businesses: ¥32 billion
(FY2019/12)

After the acquisition of shares, all sales including CMO business are recorded in P&L of Nichi-Iko Group.

*With some exceptions

Basic method of succession

Successor	Nichi-Iko Gifu Plant Co., Ltd.
Name	"Nichi-Iko G"
Distribution channel	Existing distribution

Fusan® for Injection (generic name: nafamostat mesilate)

Oct 1986

Launched

Apr 1, 2019

Marketing Authorization was acquired from Torii Pharmaceutical Co., Ltd.

May 18, 2020 Nafamostat was listed as an off-labeled drug in the guidance for COVID-19 treatment (2nd edition).



Link

Joint research by
Oxford University and
University of
Edinburgh

Donating product and
supplying API for research
trials

Joint R&D of inhalable
formulation of
nafamostat with the
University of Tokyo,
RIKEN, and Daiichi
Sankyo

Link

Specified clinical
research by the
University of Tokyo

Decadron Tablets (generic name: dexamethasone)

Jul 1959

Launched

Dec 27, 2010

Marketing Authorization was acquired from MSD K.K.

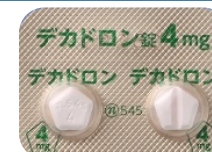
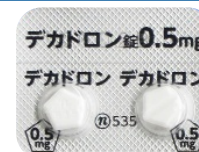
Jun 2014

4 mg tablets were launched.

Jun 16, 2020

Oxford University published a study on the efficacy of dexamethasone in severe cases of COVID-19.

Jul 17, 2020 Dexamethasone was listed as a therapeutic drug in the guidance for COVID-19 treatment (2.2 edition) in Japan.



Value of Nichi-Iko's LLP business

Together with the acquisition of products, we will take over the clinical data which have been accumulated over many years so that we can respond to the societies' needs under any circumstances backed by an extensive product lineup.

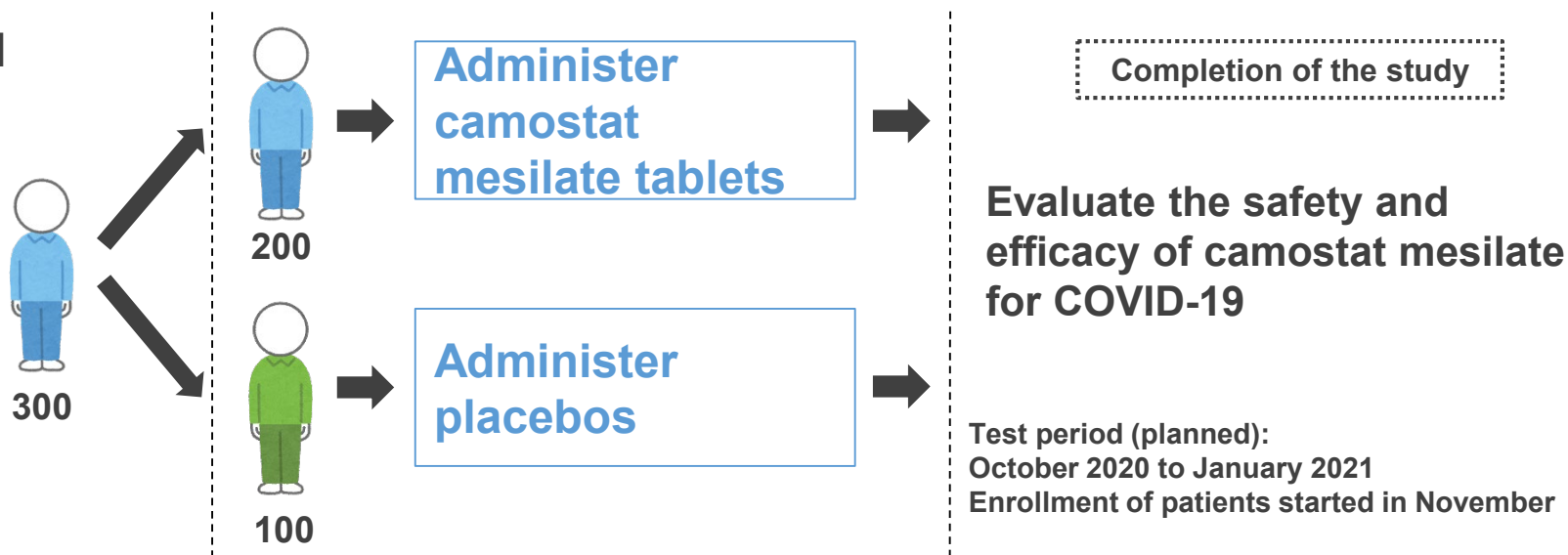
Nichi-Iko will continue to proactively engage in COVID-19 initiatives.

Start of CAMELOT Project

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



14 sites in 8 states of the U.S. currently participating (target: 20 sites)

New Products

Products listed in June 2020:
11 molecules with 21 SKUs



Eldecalcitol

2 competitors



Pirfenidone
Only One GE



Celecoxib
Top GE share

FY2021/3 1H
Sales actual/plan

2.3 / 10 billion yen

(Sales results as of the end of the first half)
(including consignment)

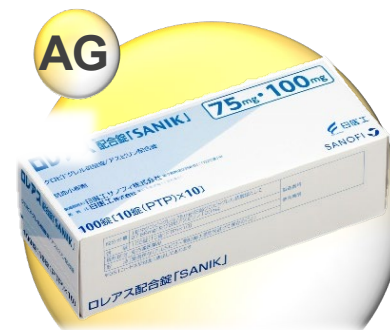
Products to be listed in December 2020:
5 molecules with 15 SKUs to be launched
AG lineup expanded to 5 products



PusoFeki



Pregabalin



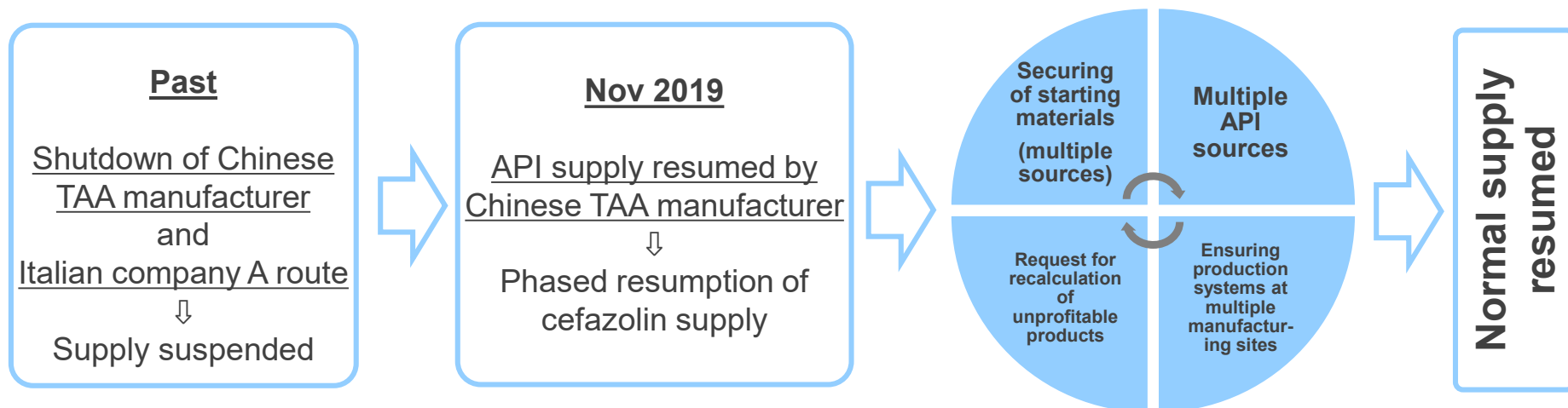
LoreAce

Execute the sales plan for listed products and
consigned products in H2

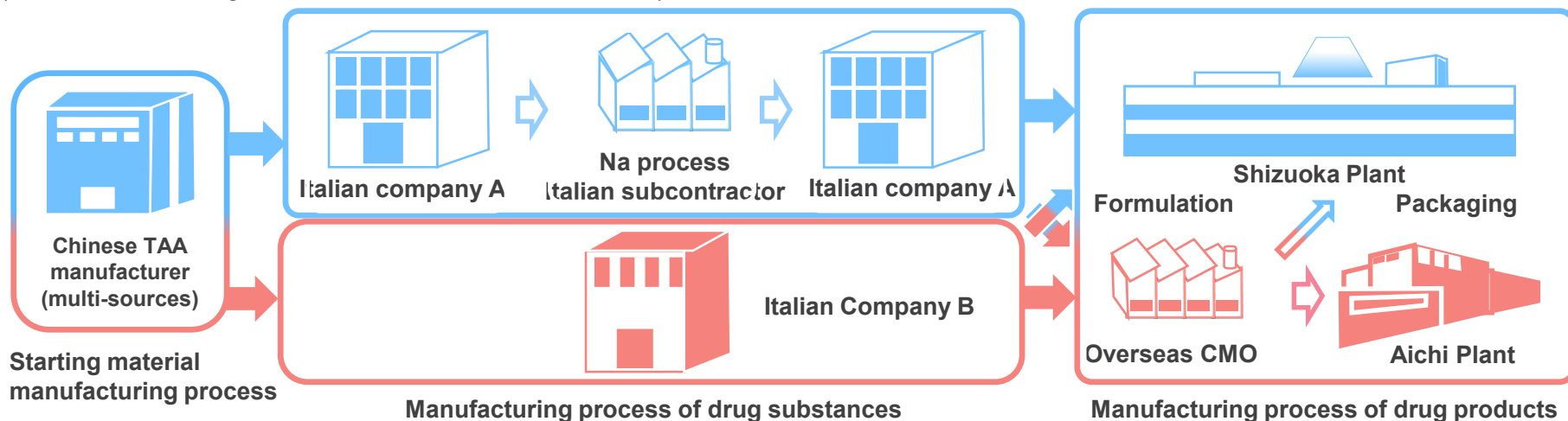
→ To achieve the new products sales target
of ¥10 billion

Process to ensure stable supply of cefazolin

Product supply in stages from November 2019 → Initiatives to ensure stable supply → Normal supply resumed on October 1, 2020



(Abbreviations in the figure: Na - sodium, TAA - tetrazole acetate)



Infliximab BS (US)

2020: Completed Phase III
Interchangeability



To resume scale-up by
dispatching consultants
2021: Scheduled to file
for FDA

Bevacizumab BS (Japan)

2020: Scheduled to file for PMDA
in November 2020 using overseas data



2022: Scheduled to be
approved by PMDA

Molecule	Market	Mkt size (100M JPY)	Pre-clinical	Phase I	Phase III	Filing/Approval
Infliximab	US	4,000	Phase III completed			CY2021 Scheduled to file
Bevacizumab	Japan	950	Scheduled to file in November 2020			Nov 2020 Scheduled to file

Strategic Alliance & Joint Venture with Medpeer



Started in September 2020



Nichi-Med Co., Ltd.
Joint venture established
on September 17, 2020

Started in November 2019



Service Linkage

**Platform to support from
medical treatment to medication follow-up**



Primary care clinic



Family pharmacy



Patients and Families

Clinic PR	Interactive chat	Medical service reservation
Online medical service	Other functions	

Send prescription data	Medication consultation	Medication follow-up	Electronic drug handbook
Online medication advice	GE price gap report	Deglutition support	Electronic payments

CO₂ reduction initiatives

At Toyama Plant 1,
raw fuel for heating and air conditioning was switched from **kerosene** to **LNG**
and
all existing kerosene boilers were replaced with **high-efficiency gas boilers**.



Reduced CO₂ emissions by approximately 30%

*LNG: Liquefied Natural Gas



LNG storage tanks (100 kL × 2 units)



Gas boilers to be newly installed (18 units)



***Preparation in progress with the aim of completing construction
and starting operations by the end of FY2021/3**

**Going forward, Nichi-Iko will promote environmentally
conscious energy-saving measures.**

Regional Comprehensive Collaboration Agreement

To date, Nichi-Iko Group has concluded regional collaboration agreements with 18 cities. We will continue to work on to solve social and local issues that we can address as a pharmaceutical company.



Namerikawa City Aug 23, 2019

Matsudo City Aug 30, 2019

Toyama City Nov 8, 2019

Imizu City Dec 6, 2019

Takaoka City Jan 17, 2020

Inabe City Feb 12, 2020

Matsuzaka City Feb 12, 2020

Tomakomai City Mar 24, 2020

Nonoichi City Mar 26, 2020

Kitahiroshima City Apr 9, 2020

Kahoku City Jul 10, 2020

Oyabe City Aug 28, 2020

Yoshikawa City Sep 30, 2020

Uozu City Oct 6, 2020

Nirasaki City Oct 8, 2020

Takayama City Oct 13, 2020

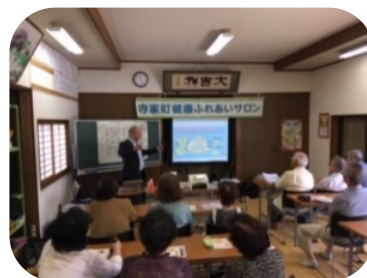
Nanto City Oct 21, 2020

Himi City Oct 22, 2020

UPDATE



Seminar delivered to the officials of the city concluded the agreement



As of May announcement:
→ Now:

10 cities
18 cities



FY2021/3 Full Year Forecast

- Sales and core operating profit were revised to reflect the 1H results and the impacts of COVID-19.
- As it is difficult at this time to calculate the impact of the acquisition of Takeda Teva's generics business, the full-year forecasts for operating profit and net income have not been determined and will be announced promptly when available.

(Million JPY)	FY2021/3	
	Initial	Revised
	full-year forecast	full-year forecast
	Consolidated	Consolidated
Sales	199,000	190,000
Core Operating Profit	7,500	6,500

Annual dividend (planned) 30.0 JPY	R&D investment 11.4 B JPY (FY2020/3 13.7 B JPY)
Capital expenditures 9.3 B JPY (FY2020/3 8.4 B JPY)	Depreciation 11.2 B JPY (FY2020/3 11.8 B JPY)

Uncertain factors

Takeda Teva GE business acquisition, COVID-19, exchange rate, annual drug price revision

◆ COVID-19 impact

- Continuous restriction of medical visits in the country

◆ Growth of new products

- Products listed in June 2020
- Products to be listed in December 2020 (including AG 2 molecules)
- Growth of limaprost alfadex (AG)

◆ Actions for COVID-19 in the U.S.

- Increasing supply of COVID-19 related products

◆ Increasing manufacturing of SterRx products and expanding the lineup

◆ Launching multiple products in the U.S.

*As for Takeda Teva's GE business and the Gifu Plant, all shares of the splitting company are scheduled to be acquired in February 2021.

*The above forecasts are based on information available as of the announcement date. Actual results may differ from these forecasts due to a variety of factors.

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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