



Nippon Chemiphar Co., Ltd.

(TSE 4539)

Highlights of FY2020 Business Results

(Year ended March 31, 2021)

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I. Summary of Results

Sales, Income

(¥mn)

	FY2019		FY2020				FY2020 (Forecast*)	
	Amount	% of Sales	Amount	% of Sales	YOY Amount	Change (%)	Amount	Achieved (%)
Net Sales	31,756	100	31,541	100.0	(214)	(0.7)	31,000	101.7
Pharmaceutical products	30,632	96.5	30,423	96.5	(208)	(0.7)	—	—
Others	1,123	3.5	1,117	3.5	(6)	(0.5)	—	—
Cost of sales	19,200	60.5	20,097	63.7	896	4.7	—	—
				[+3.2p]				
SG&A expenses	12,190	38.4	10,879	34.5	(1,311)	(10.8)	—	—
				[Δ3.9p]				
Operating income	364	1.1	564	1.8	199	54.8	200	282.3
Income before income taxes and minority interests	732	2.3	713	2.3	(18)	(2.6)	—	—
Net income attributable to owners of the parent	436	1.4	495	1.6	58	13.4	50	x10

*Revised forecast issued on Oct 30, 2020.

Pharmaceutical Sales

(¥mm)

	FY2019		FY2020			FY2020 Forecast**	
	Amount	% of Sales	Amount	% of Sales	YOY (%)	Amount	Achieved (%)
Total (① + ②)	27,788	100.0	27,322	100.0	(1.7)	27,040	101.0
① Generics	26,425	95.1	25,532	93.4	(3.4)	25,190	101.4
To medical institutions	25,442		24,531		(3.6)	24,200	101.4
To other makers*	983		1,000		1.8	990	101.1
Amlodipine	2,646		2,482		(6.2)	2,370	104.7
Lansoprazole	1,229		949		(22.8)	990	95.9
Donepezil	1,005		824		(18.0)	850	97.0
Rabeprazole	1,311		1,416		8.1	1,360	104.2
Limaprost Alfadex	943		728		(22.8)	740	98.4
Others	19,290		19,131		(0.8)	18,880	101.3
② Proprietary products and new drugs	1,362	4.9	1,790	6.6	31.4	1,850	96.8
Uralyt	842		730		(13.3)	740	98.8
Others	520		1,059		x2	1,110	95.5
Total (① + ③)	27,322	—	26,696	—	(2.3)	26,290	101.5
③ Generics (ODM)	896	—	1,164	—	29.9	1,100	105.8

* Includes exports

** Revised forecast issued on Oct 30, 2020.

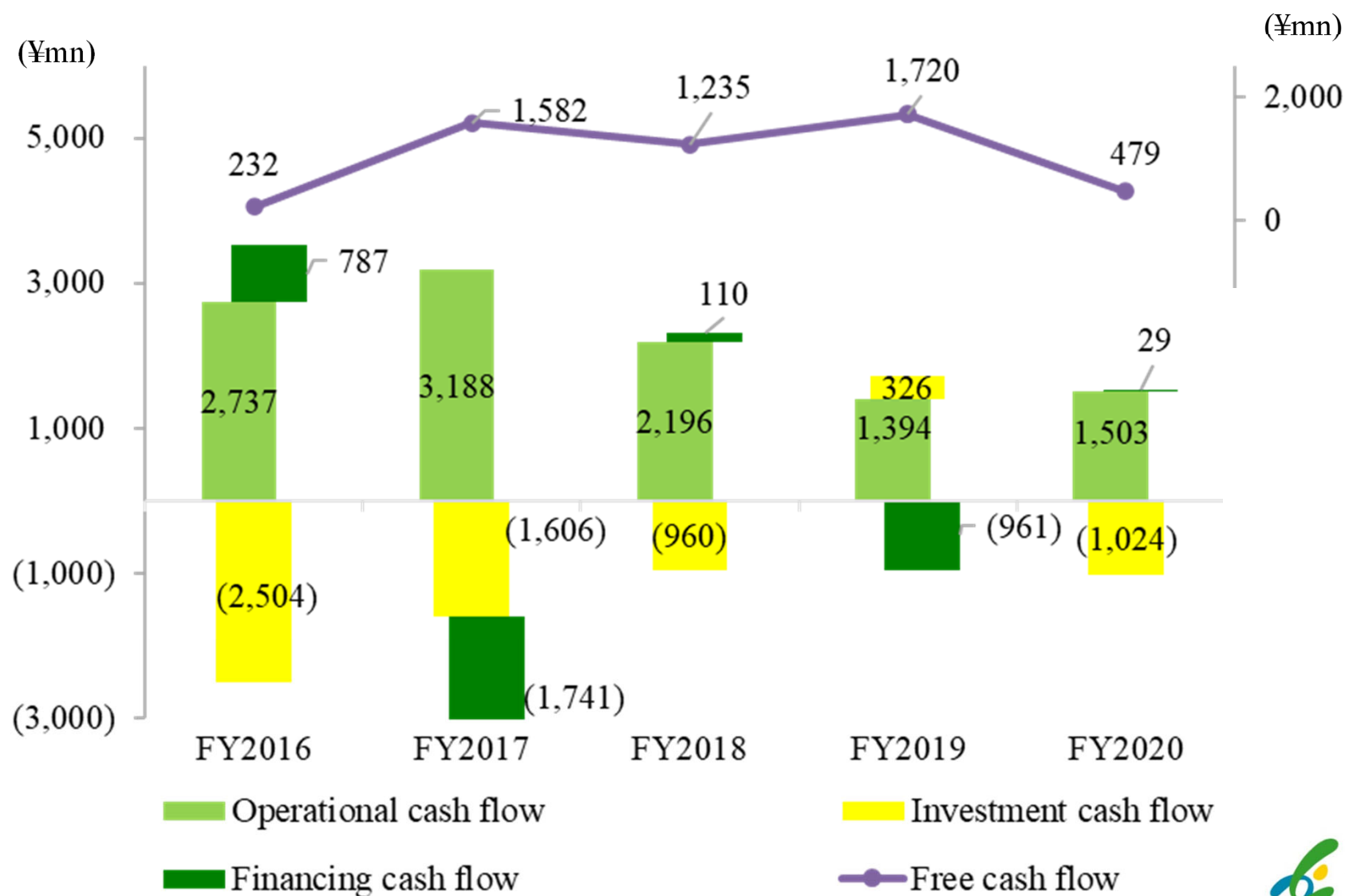
Balance Sheet

(¥mn)

	FY2019	FY2020	Change	Components	
Current assets	29,314	30,446	1,132	Cash, deposits	505
				Notes, accounts receivable-trade	660
				Inventories	235
Non-current assets	16,547	16,676	129	Buildings and structures	(381)
				Investment securities	173
Total assets	45,862	47,124	1,261		
Current liabilities	13,739	14,102	363	Notes, accounts payable-trade	344
				Short-term loans payable	(256)
				Accrued expenses	(85)
Non-current liabilities	14,730	15,006	276	Long-term loans payable	577
Net assets	17,392	18,014	622	Unrealized holding gains or loss on securities	143
Liabilities, net assets	45,862	47,124	1,261		

	FY2019	FY2020	Change
Current ratio (x)	2.13	2.16	0.03
Capital-to-asset ratio (%)	37.9	38.2	0.3

Cash Flow



II. FY2021 Forecasts

Sales, Income, R&D Expenses and Other

(¥mn)

	FY2020		FY2021 (Forecast)		
	Amount	% of Sales	Amount	% of Sales	YOY (%)
Net Sales	31,541	100.0	31,000	100.0	—
Operating income	564	1.8	350	1.1	—
Income before income taxes and minority interests	713	2.3	—	—	—
Net income attributable to owners of the parent	495	1.6	80	0.3	—

Note:

We plan to apply “the Accounting Standards for Revenue Recognition (ASBJ Statement No. 29)” from the FY2021, and the consolidated financial forecast for the FY2021 incorporates these changes. Therefore, year-on year rate from the actual results for the FY2021 before the application of the standards, etc. is not stated.

Main factors driving changes in net sales

- (-) NHI drug price reduction in April 2021
- (-) Tendency for patients to refrain from medical examinations in the midst of the COVID-19 pandemic.
- (+) Sales channel diversification efforts
- (+) Full-year contributions from Klaricid
- (+) Launching new generics

Main factors affecting income

- (-) Decline in gross profit caused by NHI drug price reduction
- (-) R&D expenses for phase 1 trial for NC-2800, which supported by public funds
- (+) Full-year contributions from group structural reforms

(¥mn)

	FY2020	FY2021 (Forecast)	YOY
R&D expenses	1,998	2,400	401
Capital expenditure	676	1,000	323
Depreciation and amortization	1,192	1,300	107

Pharmaceutical Sales Forecast

(¥mn)

	FY2020		FY2021 (Forecast)		YOY (%)
	Amount	% of Sales	Amount	% of Sales	
Total	27,322	100.0	26,550	100.0	—
Generics	25,532	93.4	24,700	93.0	—
To medical institutions	24,531		23,600		—
To other makers*	1,000		1,100		—
Proprietary products and new drugs	1,790	6.6	1,850	7.0	—
Uralyt	730		580		—
Others	1,059		1,270		—
Total	26,696	—	25,410	—	—
Generics (ODM)	1,164	—	710	—	—

* Includes exports

Note:

We plan to apply “the Accounting Standards for Revenue Recognition (ASBJ Statement No. 29)” from the FY2021, and the consolidated financial forecast for the FY2021 incorporates these changes. Therefore, year-on year rate from the actual results for the FY2021 before the application of the standards, etc. is not stated.

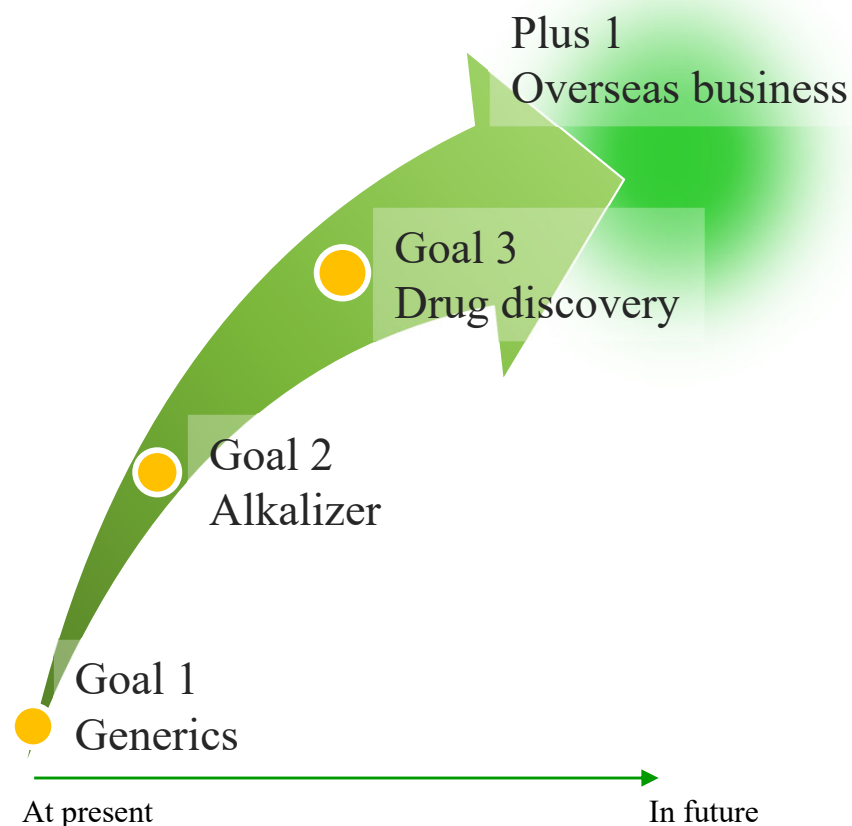
III. Management Strategy

Three Plus 1 Principal Goals

Overview

Business strategy by Three Principal Goals

- By fulfilling our three principal goals, we will establish a proprietary business model.
- To make that growth sustainable, we are expanding our business internationally.



Goal 1: Generics

Develop unique business by differentiating our products and enhance cost competitiveness.

Goal 2: Alkalizer

Apply the results of clinical research on alkalization therapy to the fullest extent possible.

Goal 3: Drug discovery

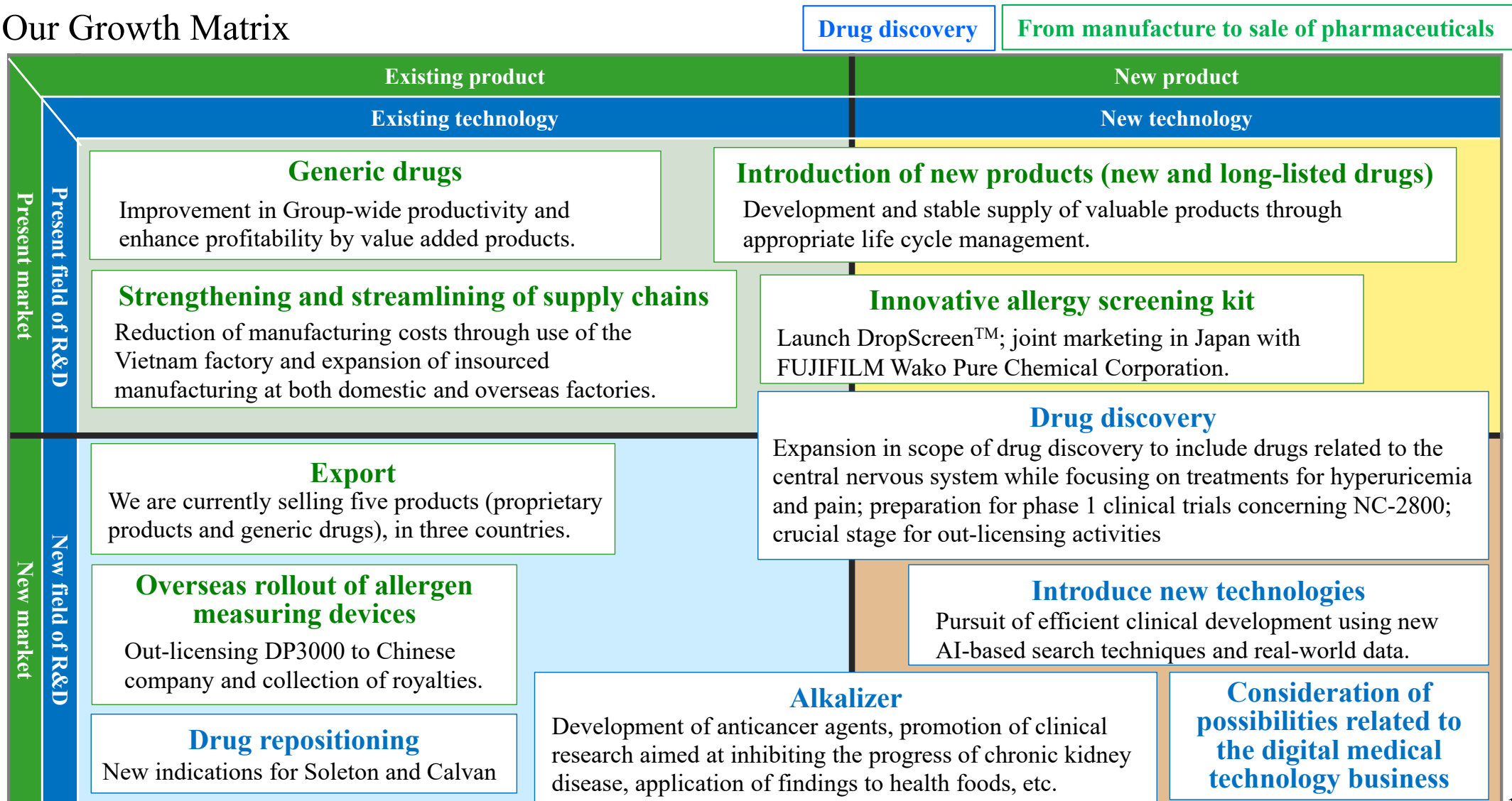
Simultaneously reduce risk, improve drug discovery efficiency, and launch new drugs on a global scale by focusing on exploratory research and out-licensing our findings at an early stage.

Plus 1: Apply our three goals to overseas markets centered on Asia

Management Strategy 1

We are developing a multi-faceted strategy for expanding our Pharmaceutical Products business that is grounded in our three plus 1 principal goals.

Our Growth Matrix



Management Strategy 2-a

Many parallel activities leads to achieve our three plus 1 principal goals.
We show timeline from FY2021—2030.

Goal	Contents	Activity	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Generics	For domestic market	Launch value-added generics and introduce products from other company	Aim to launch two or more value-added products per year.									
Alkalizer	New applications for alkalizer	DFP-17729	Phase 1/2 for pancreatic cancer	Phase 3	Application, approval, and launching							
		Consider expanding applications to include additional chronic kidney disease-related indications	PMDA counseling and consultations	Examine new potential therapeutic use for chronic kidney disease-related indications, move to clinical phase (Attempt to shorten clinical trial terms and cut costs cutting by analyzing real world data with AI.)								Application, approval, and launching
		For functional foods and health foods	Launching four products during FY2022–2025					Sequentially launch two other health-related products.				

Management Strategy 2-b

Goal	Contents	Activity	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Drug discovery	Licensing out activities	NC-2800: Conduct phase 1/ 2a trials, out-licensing	Conduct phase 1/ 2a trials in accordance with AMED's CiCLE program						Conduct phase 2b/ 3 trials by the licensee company			
		NC-2600: Out-license for new indications			Promptly out-license as a treatment for chronic coughing and contribute to earnings through the achievement of milestones.							
		NC-2500/NC-2700: Progress to phase encompassing out-licensing activities and development			Out-licensing of NC-2500 for new indications in addition to gout and hyperuricemia. Push NC-2700 to the development stage through fundraising, etc.							
	Create new compound	Discover new compounds by utilizing AI	Create new compounds		Preclinical phase/ License out		Discovery of new compounds continuously through new methods					
Overseas business	Pharmaceuticals	From export to local development and production	Sell five products to 4 countries		Sell ten products to 5 countries		Ongoing efforts aimed at expanding our product lineup and the number of countries in which these products are sold.					
					Manufacture six products in Vietnam		Gradually focus to a business model predicated on highly profitable local development and manufacture.					
	Diagnostics	Licensing business of DP3000 and IgE NC in the Chinese market	Intermediate goods associated with IgE NC		Addition of 36 approved items for measurement				Ongoing subsequent addition of approved items for measurement			
		Sales expansion of Drop Screen	Expand domestic market		Aim to achieve continuous business expansion through launching series of measuring reagents							
			Development of an overseas reagent lineup		Sequential launch in Europe and the Americas and then in Asia							

Generic Business

Responding to rapid changes in business environment and converting to a business structure that will achieve sustainable growth in all environments.

Development

Shift focus of development from large-scale products to value-added drug formulations. Launch two or more products per year which meet clinical needs, niche products, and products related to patent strategies.

Manufacture

Reduce cost of sales by expanding production at the Vietnam factory (aiming 30% of volume) and cutting manufacturing costs through the addition of high-quality and affordable APIs from overseas while securing stable means of supply.

In support of quality assurance, conduct regular audits of Group manufacturing sites and external manufacturing subcontractors that are in accordance with ministerial ordinances and confirm that production management and quality control are being performed in keeping with the three principles of good manufacturing practice; at Group manufacturing sites, implement raw material management performed through barcode systems or doublechecking policies, annual product quality reviews, and quality risk management.

Sale

Established a Group Pharmaceutical Sales Headquarters that centrally supervise pharmaceutical sales divisions within both the Company and its subsidiary NPI*.

Slimmed down our organization through the consolidation of branch offices.

In addition to conventional wholesale channels, adopt a variety of other sales channels (distributors, etc.) for generic drugs and increase opportunities for the direct sale of certain products.

Invest in digital transformation to support post-COVID-19 workstyles and raise the productivity of corporate activities; through sales force automation, optimize and accelerate PDCA cycles associated with sales activities aimed at persuading medical institutions and other similar organizations to use our products.

Quality Assurance Generic Business

We implemented the following initiatives in response to quality issues associated with the products of other companies:

Special internal investigations

January 2021: Conducted internal investigations at three factories operated by NPI*

At each factory, we conducted investigations into the potential use of incorrect raw materials, the possible presence of procedure manuals containing unapproved instructions, and systems for communicating with superiors when tests and inspections return abnormal values.

None of these investigations uncovered any issues.

February 2021: Distributed information to medical professionals

Both Nippon Chemiphar and Nihon Pharmaceutical Industry Co., Ltd. distributed information regarding supervisory and production management systems to medical professionals.

Enhancement of management systems

Personnel changes effected on April 1, 2021

We strengthened our management's commitment to quality by appointing a Chief Pharmaceutical Officer.

Setting common quality standards for the Group

We will set common good manufacturing practice standards for the entire Group and strive to strengthen our quality assurance system through efforts aimed at unifying separate quality assurance systems throughout the Group.

Development of New Applications for Alkalizer

We are conducting multi-faceted development using technologies and expertise related to alkalization that we cultivated over many years through our involvement with urine Alkalizer.

For pharmaceuticals

Anti-cancer agent DFP-17729 moves to phase 2a clinical trial

DFP-17729 which we concluded a licensing agreement with drug discovery venture Delta-Fly Pharma, Inc. conducts clinical trial for patients suffering from late-stage pancreatic cancer. In April 2021, it moved to phase 2a.

Promote clinical research for preventing progress of chronic kidney disease













We are currently utilizing AI and clinical data to conduct additional analysis of results generated by the CKOALA study conducted at Tohoku University, which focused on the renoprotective effects of oral alkalizers in patients of chronic kidney disease. We expect to be presented the results of these analyses at conferences within FY2021 and seek possibility to expand indication.

Investigation regarding possible applications in functional foods and health foods

Based on research data and our expertise regarding alkalization therapy, we are also developing functional foods with domestic food manufacturers and plan to launch during 2022-2025.

Pipeline

 In-house drug development  Other companies or physician-initiated development

Item	Function (Target)	Pre-clinical	Phase 1	Phase 2	Notes
NC-2400	PPAR-δ agonist (Lipid metabolism abnormalities)				<ul style="list-style-type: none"> Finished Phase 1. Licensed to Abionyx Pharma SA (France).
NC-2500	XOR inhibitor (Hyperuricemia, gout)				<ul style="list-style-type: none"> Phase 1 was finished and we are conducting licensing out activities. Explored possibilities for applications as a treatment for neurodegenerative diseases.
NC-2600	P2X4 receptor antagonist (Neuropathic pain)				<ul style="list-style-type: none"> Phase 1 was finished and we are conducting licensing out activities. Also began out-licensing for application as a treatment for chronic coughing.
NC-2700	URAT1 inhibitor (Hyperuricemia, gout)				<ul style="list-style-type: none"> Finished preclinical trial and we are conducting licensing out activities.
NC-2800	δ opioid receptor agonist (Depression/Anxiety)				<ul style="list-style-type: none"> Selected by AMED for its funding program on January 2018. Conducting out-licensing activities ahead of a phase 1 clinical trial launch planned for FY2021.
DFP-17729	Cancer microenvironment improving agent (Pancreatic cancer)				<ul style="list-style-type: none"> Developed by Delta-Fly Pharma, Inc. From April 2021, moved to phase 2 trial.
Soleten	COX inhibitor (Diffuse-type tenosynovial giant cell tumor and others)				<ul style="list-style-type: none"> Physician-initiated clinical trial was started. Achieved the objective number of trial participants and plan to conduct data analysis.
Calvan	Alβ1 blocker (Huntington's disease)				<ul style="list-style-type: none"> Licensed to SOM Biotech SL (Spain). Finished phase 2a trial.

As of March 2021.

Diagnostics Business

We have begun to consider an overseas rollout of DropScreen™ as we strive to expand its application within the domestic market. Additionally, we have begun collaborating with local partners as we promote allergy testing reagent Oriton IgE Chemiphar™ in China.

Launched allergy screening kit Drop Screen™ in Japan

- Breakthrough measuring equipment that is capable of screening blood samples taken from fingertips for 41 allergens within 30 minutes.
- We received a favorable volume of inquiries from medical institutions considering implementation of the system despite restrictions placed on informative activities by the COVID-19 pandemic.
- During FY2021, we plan to start specific consideration for overseas rollout.

DropScreen™ measuring device A-1



Rollout of IgE NC in China



IgE NC

- Commercial sales have been started in FY2020. Plan to full-scale promotion in FY2021.
- We provide core components and technologies to indigenous companies attempting to localize their production and earn royalty income commensurate with sales revenue.

Overseas Business

Apply our three goals to overseas markets centered on Asia.

Development of Calvan tablets in China

- In 2020, Calvan tablets were included as a standard treatment option in guidelines set by an authoritative Chinese academic society supporting research concerning high blood pressure.



lecture for the launching Calvan tablets.
(April 2021, Chengdu City in China)

Activity in Vietnam



Vietnam factory

- Develop channels with the goal of executing sales in Vietnam where our factory is located and in neighboring countries
- Begin development of pharmaceutical products targeting ASEAN markets through Nippon Chemiphar Vietnam

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Note about Forward-looking Statements and Forecasts

Statements made in this *Highlights of Business Results*, with respect to current plans, estimates, strategies and beliefs, and other statements of Nippon Chemiphar that are not historical facts are forward-looking statements about the future performance of Nippon Chemiphar.

These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. Consequently, undue reliance should not be placed on these statements.

Nippon Chemiphar cautions the reader that a number of important factors could cause actual results to differ materially from those discussed in the forward-looking statements.