



Nippon Chemiphar Co., Ltd.

(TSE 4539)

# Highlights of Second Quarter FY2021 Business Results

(Year ending March 31, 2022)

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# I. Summary of Results

# Sales, Income

(¥mn)

	FY2020		FY2021		YOY		Fullyear Forecast	Progress Rate (%)
	2Q Amount	% of Sales	2Q Amount	% of Sales	Amount	Change (%)		
<b>Net Sales</b>	<b>14,832</b>	<b>100.0</b>	<b>15,575</b>	<b>100.0</b>	—	—	<b>31,000</b>	<b>50.2</b>
Pharmaceutical products	14,569	98.2	15,115	97.0	—	—	—	—
Others	262	1.8	460	3.0	—	—	—	—
Cost of sales	<b>9,446</b>	<b>63.7</b>	<b>11,265</b>	<b>72.3</b>	—	—	—	—
SG&A expenses	<b>5,575</b>	<b>37.6</b>	<b>4,103</b>	<b>26.3</b>	—	—	—	—
				8.6p				
				(11.3p)				
<b>Operating profit/loss</b>	<b>(189)</b>	—	<b>206</b>	<b>1.3</b>	—	—	<b>350</b>	<b>58.9</b>
<b>Profit/loss before income taxes and minority interests</b>	<b>346</b>	—	<b>258</b>	<b>1.7</b>	—	—	—	—
<b>Profit/loss attributable to owners of the parent</b>	<b>(257)</b>	—	<b>228</b>	<b>1.5</b>	—	—	<b>80</b>	<b>286.2</b>

(Reference) Year-on-Year Comparisons Utilizing Previous Accounting Standards  
(¥mn)

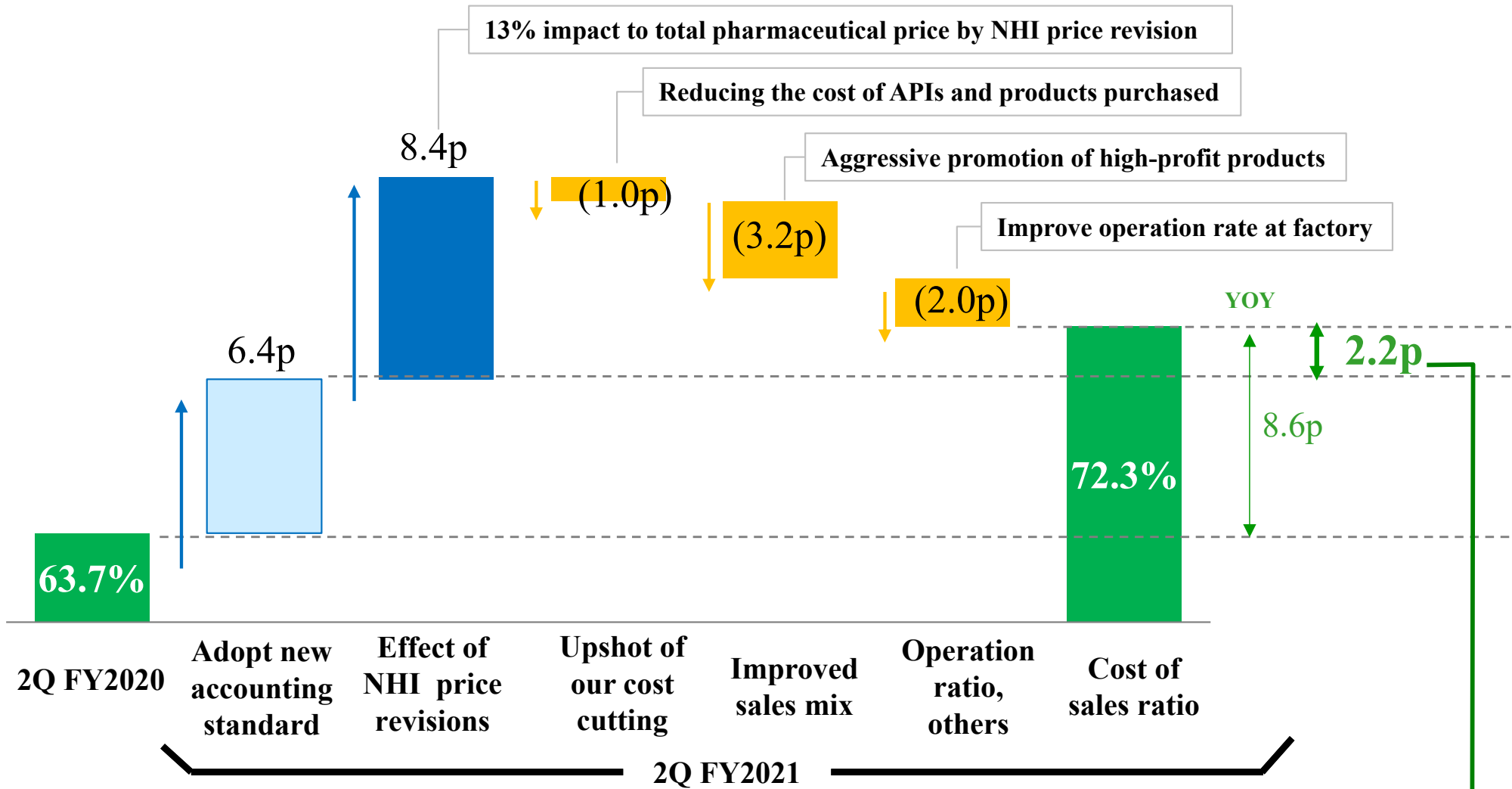
	FY2020	FY2021	YOY*	
	2Q Amount	2Q Amount*	Change	%
<b>Net Sales</b>	<b>14,832</b>	<b>17,110</b>	<b>2,277</b>	<b>15.4</b>
Pharmaceuticals	14,569	16,675	2,105	14.5
Others	262	434	172	65.6

Note:

We applied “the Accounting Standards for Revenue Recognition (ASBJ Statement No. 29)” from the FY2021.

Therefore, year-on year rate from the actual results for the FY2020 before the application of the standards, etc. is not stated.

# Reason for Rising Cost of Sales Ratio



Without impact of new accounting standard, cost of sales ratio up only 2.2 percentage points by our effort to improve sales mix or cost cutting.

# Pharmaceutical Sales

(¥mn)

	FY2020		FY2021				
	2Q Amount	% of Sales	2Q Amount	% of Sales	YOY (%)	Fullyear Forecast	Progress Rate (%)
<b>Total(① + ②)</b>	13,059	100.0	13,468	100.0	—	26,550	50.7
<b>① Generics</b>	12,284	94.1	12,581	93.4	—	24,700	50.9
To medical institutions	11,810		12,010		—	23,600	50.9
To other makers	474		571		—	1,100	52.0
<b>② Proprietary products and new drugs</b>	775	5.9	887	6.6	—	1,850	48.0
Uralyt	377		317		—	580	54.7
Others	397		569		—	1,270	44.9
<b>Total(① + ③)</b>	12,953	—	12,984	—	—	25,410	51.1
<b>③ Generics (ODM)</b>	668	—	402	—	—	710	56.7

Note:

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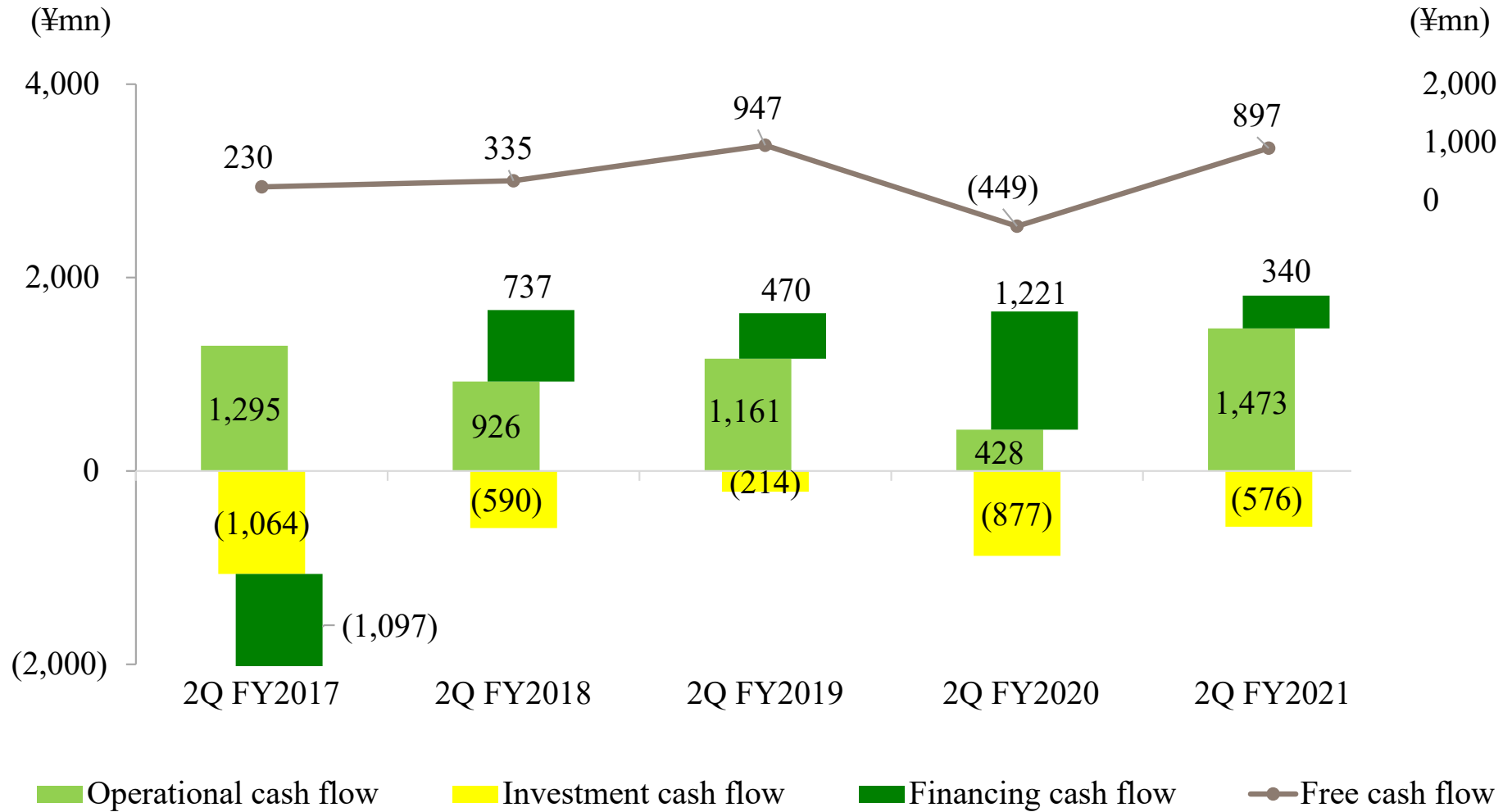
# Balance Sheet

(¥mn)

	March 31, 2021	September 30, 2021	Change	Components	
<b>Current assets</b>	30,446	31,850	1,403	Cash, deposits	1,320
				Notes, accounts receivable-trade	(286)
				Inventories	376
<b>Non-current assets</b>	16,676	16,679	2	Buildings and structures	(56)
				Investments in securities	(52)
<b>Total assets</b>	<b>47,124</b>	<b>48,530</b>	<b>1,406</b>		
<b>Non-current liabilities</b>	14,102	14,575	472	Notes, accounts payable-trade	1,266
				Loans payable	101
				Accrued expenses	(366)
<b>Current liabilities</b>	<b>15,006</b>	<b>15,751</b>	<b>744</b>	Long-term loans payable	479
<b>Net assets</b>	<b>18,014</b>	<b>18,203</b>	<b>188</b>	Valuation difference on available-for-sale securities	(50)
<b>Liabilities, net assets</b>	<b>47,124</b>	<b>48,530</b>	<b>1,406</b>		

	March 31, 2021	September 30, 2021	Change
<b>Current ratio (x)</b>	2.16	2.19	0.03
<b>Capital-to-asset ratio (%)</b>	38.2	37.5	(0.7)

# Cash Flow





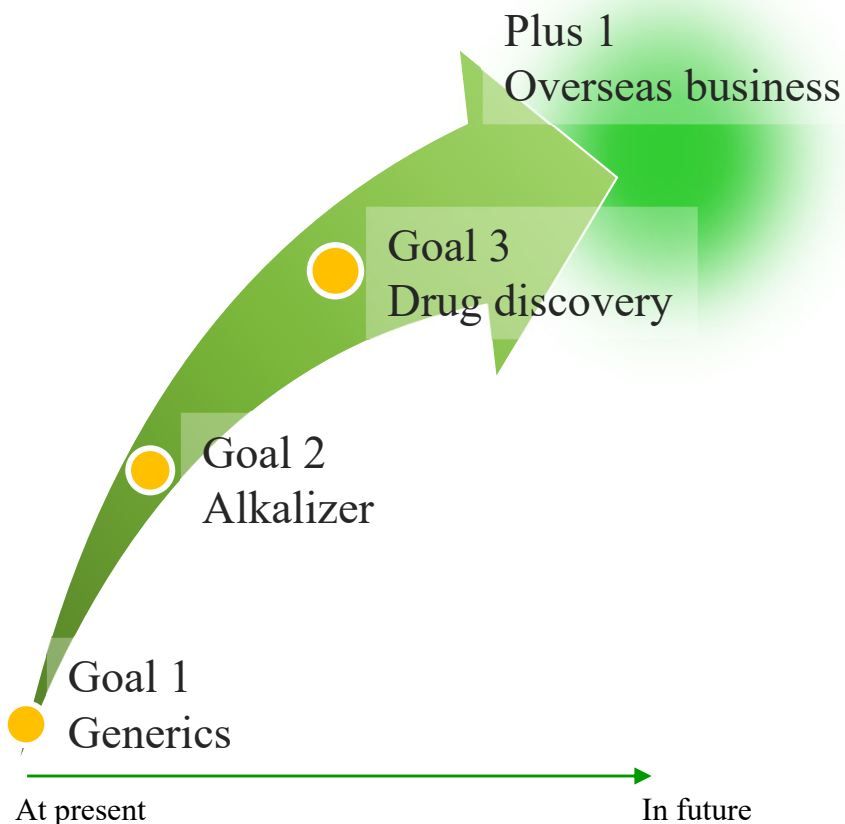
## **II. Management Strategy**

# 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 our expertise concerning alkalization therapy and the results generated through corresponding clinical research to the treatment of cancer and chronic kidney disease.

#### 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.

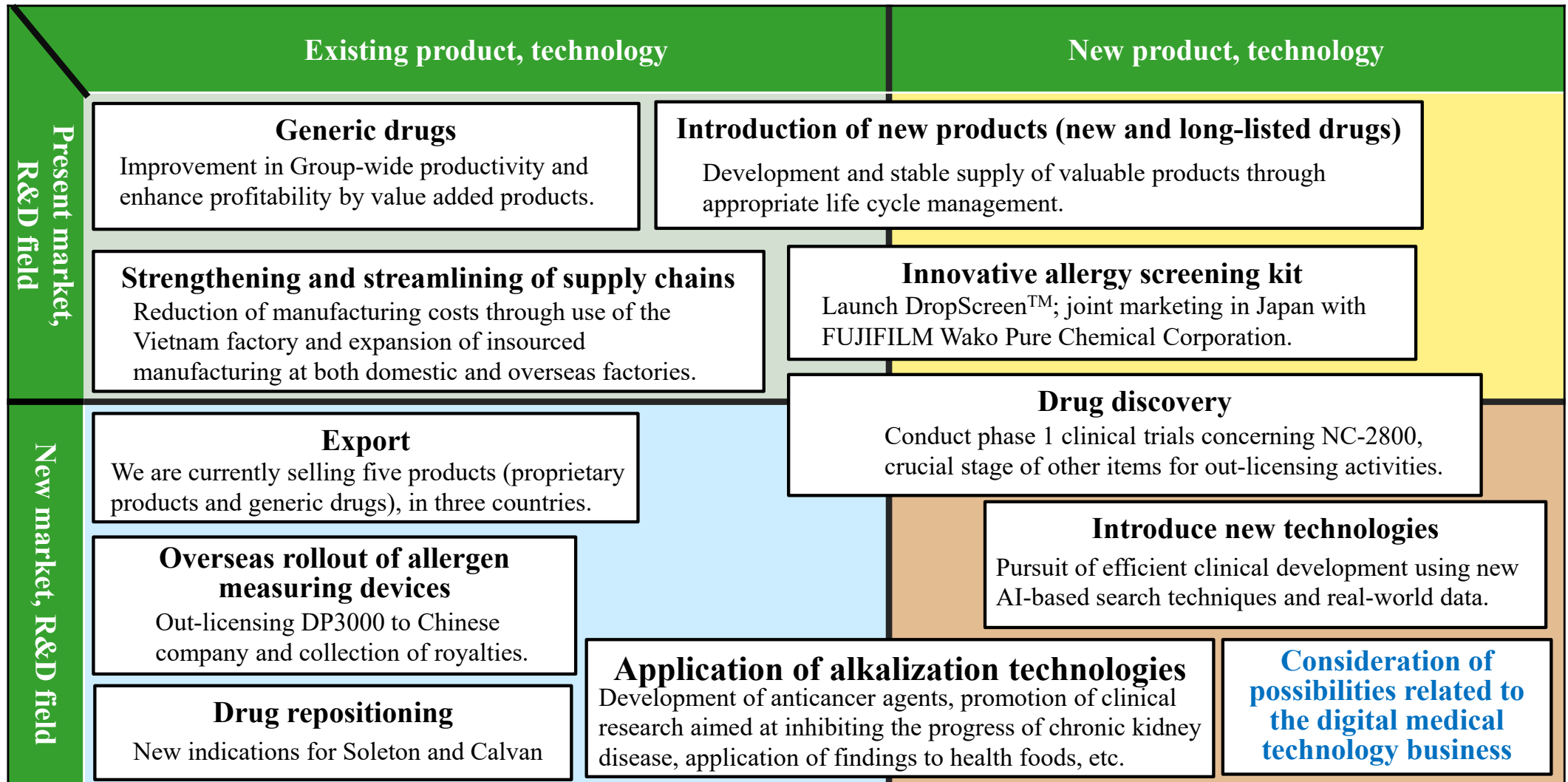
#### Plus 1: Overseas Business

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 anticancer agent	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 (Try to cut time for clinical trials and costs by analyzing real world data with AI.)									Application, approval, and launching
		Utilize technology and knowledge to make functional foods and trademarked products		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	NC-2800: Conduct phase 1 and 2a trials; out-license	Conduct phase 1 and 2a trials in accordance with AMED's CiCLE program						Licensee Company will conduct phase 2b and 3 trials				
		NC-2600: Out-license for new applications	→		Out-license as a treatment for chronic cough, contribute to earnings through the achievement of milestones.								
		NC-2500/NC-2700: Progress out-licensing activities and development	→		Out-license 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	→		Preclinical phase/ License out		Discovery of new compounds through the application of new methods.						
Overseas business	Pharmaceuticals	From export to local development and production	→		Sell 10 products to five countries		Ongoing efforts aimed at expanding our product lineup and the number of countries in which these products are sold						
	Diagnostics	License DP3000- and IgE NC-related business 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			
		Expand sales of DropScreen™	→		Expand domestic market		Aim to achieve continuous business expansion through creating new series of measuring reagents.						
			→		Development of an overseas reagent lineup		Sequential launch in Europe, the Americas and 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 and 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.

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- We aim to set good manufacturing practice standards for the entire Group.
  - Strengthen our manufacture and quality assurance system, including the recruitment of additional staff.

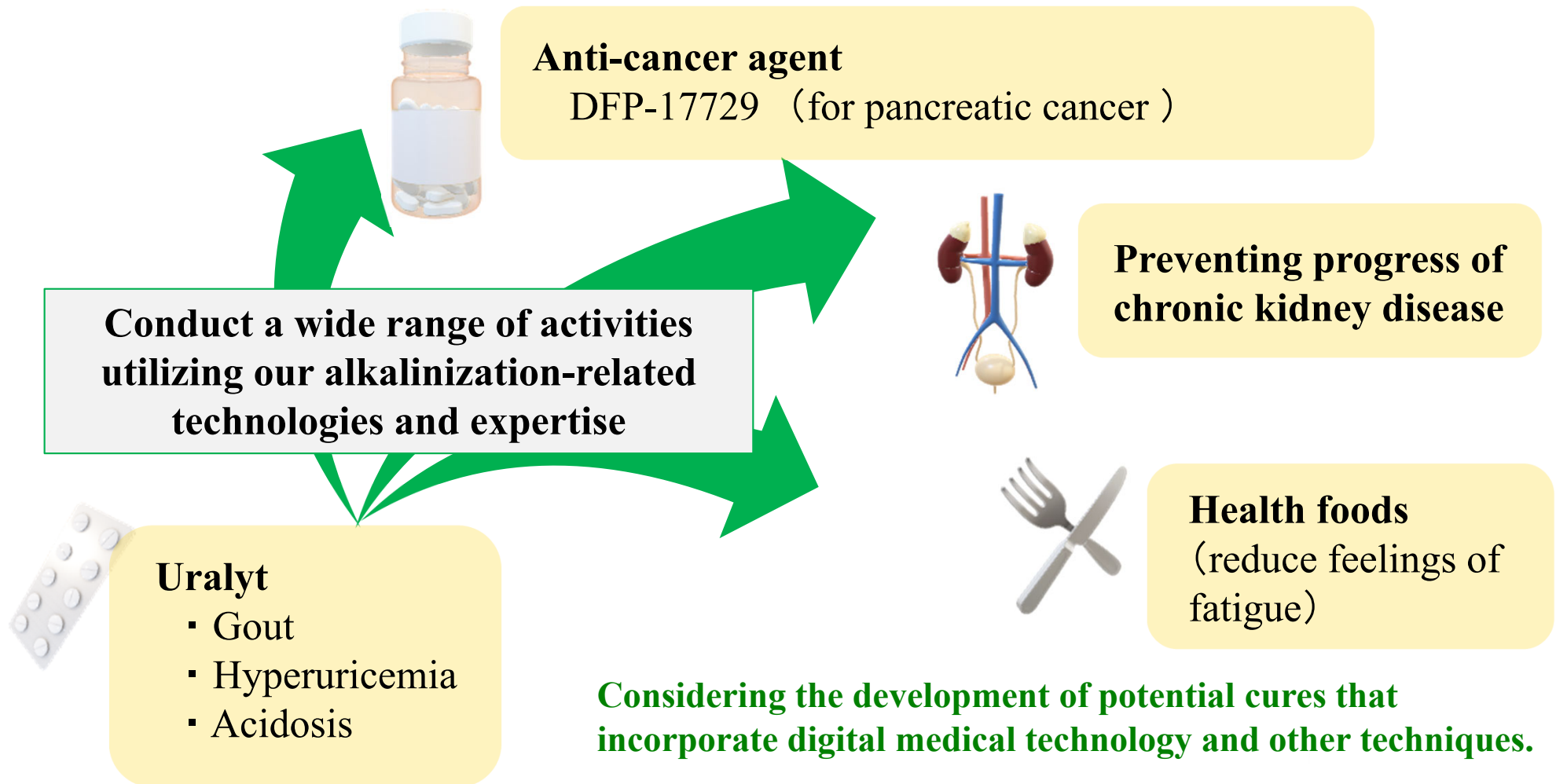
## Sale

The Group Pharmaceutical Sales Headquarters centrally supervises pharmaceutical sales divisions within both the Company and its subsidiary NPI\* and supports a diverse range of sales channels; to support post-COVID-19 workstyles and raise the productivity of our corporate activities, we strive through our new sales force automation system to optimize and accelerate PDCA cycles associated with sales activities.

# Alkalizer

We are conducting multi-faceted development using alkalization-related technologies and expertise that we cultivated over many years through activities associated with our urine alkalizer, Uralyt.

## Application of alkalization technologies

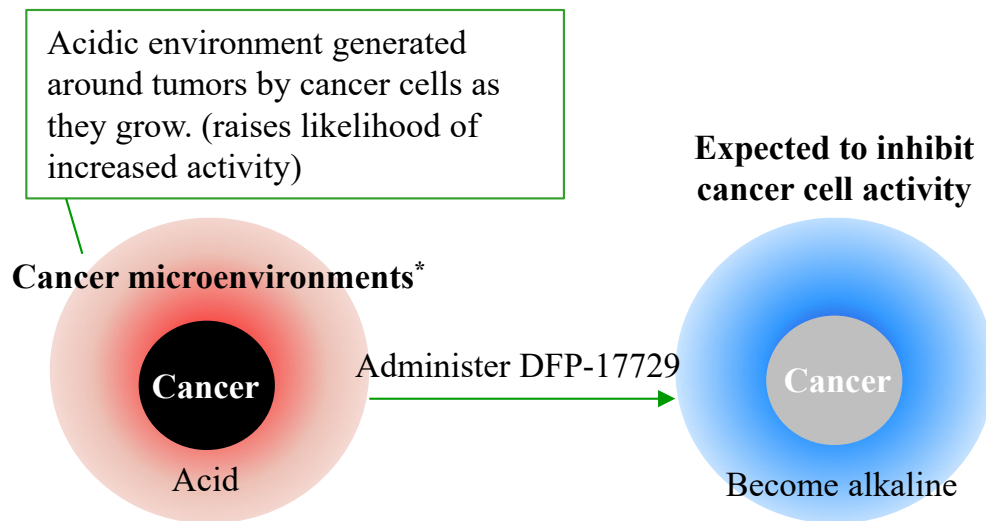


# Develop Alkalizer for Anti-cancer Agent

We have concluded a licensing agreement with Delta-Fly Pharma, Inc. (DFP) concerning DFP-17729, a cancer microenvironment improving agent that is expected to generate groundbreaking therapeutic effects by alkalizing acidic cancer microenvironments.

## Evaluating the effects of DFP-17729

- DFP-17729 improves cancer microenvironments through its alkalization effects.
- It is expected to generate groundbreaking therapeutic effects as a treatment for refractory cancer.

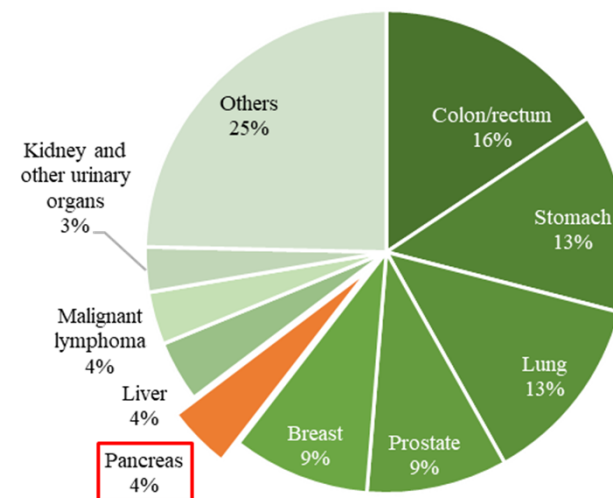


\*In contrast with healthy tissues, cancerous tissues are surrounded by distinctive environments. These are generally called “cancer microenvironments.”

## Potential applications of DFP-17729

- Pancreatic cancer accounts for 4% of all incidences of cancer.
- This drug is expected to have therapeutic effects when used in the treatment of refractory cancer. We plan to develop multiple applications for this drug while negotiating with DFP.

Projected Number of Cancer Incidence by Site (2020)



Source :CANCER STATISTICS IN JAPAN — 2021, Foundation for Promotion of Cancer Research



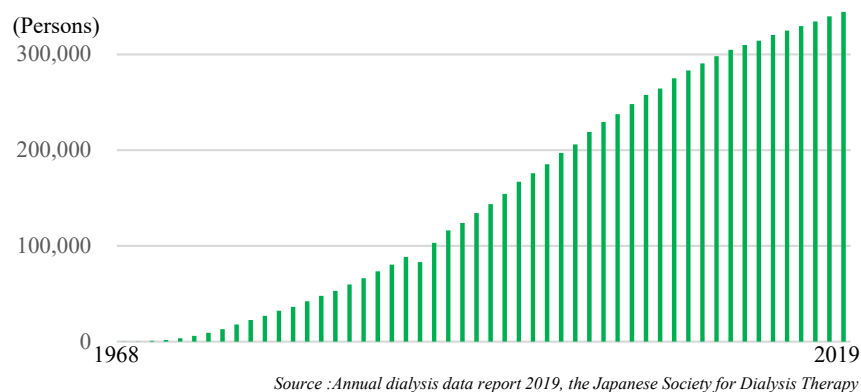
# Develop Alkalizer for CKD and Health Food

We are striving to develop uses for our alkalization technologies in treatments that inhibit the progression of chronic kidney disease (CKD) and in health food products.

## Inhibit the progression of CKD

- The potential number of CKD patients is estimated to be 13 million. CKD sufferers ultimately require dialysis once their conditions worsen. Increases in the number of patients requiring dialysis give rise to a variety of issues.
- In its Basic Policies for Economic and Fiscal Management and Structural Reform, the Japanese government has identified kidney disease as an ailment for which prevention must be prioritized.

Trends in the prevalent dialysis patient count




## Our activities

- We are supporting a CKOALA study underway at Tohoku University concerning the renoprotective effects of oral alkalizers in patients of chronic kidney disease.
- Utilizing AI and clinical data, we have completed our additional analysis of results generated through the CKOALA study.
- Based on this analysis, we are considering a variety of development possibilities targeting CKD.













## Investigation for Health Food

- Based on research data and our expertise regarding alkalization therapy, we are also developing functional foods.
- Received approval from the Consumer Affairs Agency regarding one product created utilizing sodium citrate.

# Pipeline

 In-house drug development

 Other companies or physician-initiated development

Item	Function (Target)	Pre-clinical	Phase 1	Phase 2	Notes
NC-2400	PPAR- $\delta$ agonist (Lipid metabolism abnormalities)				<ul style="list-style-type: none"> <li>Finished Phase 1.</li> <li>Licensed to Abionyx Pharma SA (France).</li> </ul>
NC-2500	XOR inhibitor (Hyperuricemia, gout)				<ul style="list-style-type: none"> <li>Phase I has ended and we are conducting licensing-out activities.</li> <li>Explored possibilities for applications as a treatment for neurodegenerative diseases.</li> </ul>
NC-2600	P2X4 receptor antagonist (Neuropathic pain, chronic cough)				<ul style="list-style-type: none"> <li>Phase 1 has ended and we are conducting licensing-out activities.</li> <li>Began out-licensing for application as a treatment for chronic cough.</li> </ul>
NC-2700	URAT1 inhibitor (Hyperuricemia, gout)				<ul style="list-style-type: none"> <li>Finished preclinical trial and are conducting licensing-out activities.</li> </ul>
NC-2800	$\delta$ opioid receptor agonist (Depression/Anxiety)				<ul style="list-style-type: none"> <li>Selected by AMED for its funding program on January 2018.</li> <li>Concluded a collaborative research and development agreement and an option agreement with Sumitomo Dainippon Pharma Co., Ltd.</li> <li>Began phase 1 in July 2021.</li> </ul>
DFP-17729	Cancer microenvironment improving agent (Pancreatic cancer)				<ul style="list-style-type: none"> <li>Developed by Delta-Fly Pharma, Inc.</li> <li>Moved to a phase 2a trial and finished case registration in November 2021.</li> </ul>
Soleton	COX inhibitor (Diffuse-type tenosynovial giant cell tumor and others)				<ul style="list-style-type: none"> <li>Physician-initiated clinical trial was started.</li> <li>Achieved the objective number of trial participants and plan to conduct data analysis.</li> </ul>
Calvan	A1 $\beta$ 1 blocker (Huntington's disease)				<ul style="list-style-type: none"> <li>Licensed to SOM Biotech SL (Spain).</li> <li>Completed the phase 2a trial and presented the data at a conference held in October 2021.</li> </ul>

# NC-2800 (Delta Opioid Receptor Agonist)

## New agreement with Sumitomo Dainippon Pharma Co., Ltd.

- Concluded a collaborative research and development agreement and an additional option agreement in June 2021
- Sumitomo Dainippon Pharma will participate in the CiCLE project as a collaborating institution and will cooperate with Chemiphar to advance the research and development of NC-2800.
- In accordance with the option agreement, Chemiphar has granted Sumitomo Dainippon Pharma the exclusive optional right to enter into a license agreement for the global development and marketing rights of this drug once its development reaches the phase 2b study stage.

## Present status and future plans

- Begin phase 1 in July 2021.
- Phase 1 protocol focuses on completing preparations necessary for international clinical studies that begin in phase 2a.
- Plan to finish phase 2a by sometime around 2026.

## Outline of NC-2800

<b>Function</b>	$\delta$ Opioid Receptor Agonist
<b>Target</b>	For depression, anxiety
<b>Character</b>	<ul style="list-style-type: none"><li>• Expected to be first-in-class due to its high levels of safety and efficacy</li><li>• Based on the results of non-clinical testing, NC-2800 is expected to be an advanced new antidepressant/anxiolytic drug that takes effect more quickly than existing drugs while generating less of the side-effects that these drugs have been known to cause (sedation, transient amnesia, dependence at prescribed dosage, etc.).</li></ul>
<b>History</b>	Created through collaborative research involving both academic and industrial entities. With support from public funding, we have conducted development of potential applications since 2013.

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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.