

# FY2023 Second Quarter Business Summary

(Year Ending March 31, 2024)



Nippon Chemiphar Co., Ltd.

(TSE 4539)

# Contents

<b>Highlights</b>	<b>2-3</b>
<b>Sales and Income</b>	<b>4-5</b>
<b>Pharmaceutical Sales</b>	<b>6-7</b>
<b>Sales Distribution by Launch Year</b>	<b>8</b>
<b>Sales of Diagnostics</b>	<b>9</b>
<b>Balance Sheet</b>	<b>10</b>
<b>Cash Flow</b>	<b>11</b>
<b>Expenditure and Per Share Information</b>	<b>12</b>
<b>Indexes</b>	<b>13</b>

<b>Three Plus 1 Principal Goals</b>	<b>14</b>
<b>Roadmap</b>	<b>15</b>
<b>New drug development: Pipelines</b>	<b>16</b>
<b>In-house Development Pipelines</b>	<b>17-18</b>
<b>In-licensing Pipelines</b>	<b>19</b>
<b>Multifaceted Development of Alkalizer</b>	<b>20</b>
<b>DropScreen</b>	<b>21</b>
<b>Overseas Business</b>	<b>23</b>

# Highlights 1

## ■ Sales

Net sales: Down 8.6% YOY, records 45.4% to full year forecast

① Pharmaceutical products: Down 13.7% YOY, records 45.7% to full year forecast

### **Factors contributing to growth in sales:**

- Growth in products released in the previous fiscal year and contribution from products released during the current fiscal year

### **Factors contributing to decline in sales:**

- Impact of NHI drug price revisions implemented in April 2023
- Impact of shipping adjustments
- Counter-reaction to sales growth driven by alternative demand during the year-ago period

② Diagnostics: Up 46.7% YOY, records 40.4% to full year forecast

- Sales increased significantly due to brisk expansion of the DropScreen allergy screening kit and reagent

## ■ Operating Profit

- Although we made efforts to reduce costs, they were not enough to fully compensate for the decline in sales, and we consequently recorded an operating loss of ¥298 million

# Highlights 2

## ■ Other Profit

- As a result of recording ¥337 million of foreign exchange gains, profit attributable to owners of parent was ¥31 million

## ■ Topics

- DropScreen installations in Japan reached 800 units as of the end of September  
(At the end of March 2024, we expect to 1,000 installations in Japan.)
- Phase I of NC-2800 has finished administration in the current period and is analyzing the data
- DFP-17729 and DFP-14323 has finished phase 2 trial and preparing for next stage

# Sales and Income to Year-on-Year

(¥mm)

	FY2022			FY2023			
	2Q Amount	% of Sales	Full Year Amount	2Q Amount	% of Sales	2Q Change	YOY (%)
<b>Net sales</b>	<b>16,237</b>	<b>100.0</b>	<b>31,559</b>	<b>14,837</b>	<b>100.0</b>	<b>(1,400)</b>	<b>(8.6)</b>
Pharmaceutical products segment	15,798	97.3	30,543	14,293	96.3	(1,505)	(9.5)
Generics, proprietary products and new drugs	13,695	84.3	26,148	11,815	79.6	(1,880)	(13.7)
Diagnostics	1,239	7.6	2,780	1,817	12.3	578	46.7
Others segment	439	2.7	1,015	544	3.7	104	23.8
<b>Cost of sales</b>	<b>11,976</b>	<b>73.8</b>	<b>23,374</b>	<b>11,204</b>	<b>75.5</b>	<b>(771)</b>	<b>(6.4)</b>
<b>SG&amp;A expenses</b>	<b>4,093</b>	<b>25.2</b>	<b>8,425</b>	<b>3,931</b>	<b>26.5</b>	<b>(162)</b>	<b>(4.0)</b>
R&D expenses	1,022	6.3	2,419	1,006	6.8	(16)	(1.6)
<b>Operating profit/loss</b>	<b>167</b>	<b>1.0</b>	<b>(241)</b>	<b>(298)</b>	<b>—</b>	<b>(466)</b>	<b>—</b>
<b>Ordinary profit</b>	<b>752</b>	<b>4.6</b>	<b>58</b>	<b>10</b>	<b>0.1</b>	<b>(741)</b>	<b>(98.6)</b>
<b>Net profit attributable to owners of parent</b>	<b>896</b>	<b>5.5</b>	<b>339</b>	<b>31</b>	<b>0.2</b>	<b>(865)</b>	<b>(96.5)</b>

# Sales and Income to Full Year Forecasts

(¥mn)

	FY2022		FY2023			
	Full Year Amount	% of Sales	2Q Amount	% of Sales	Full Year Forecasts	Progress Rate (%)
<b>Net sales</b>	<b>31,559</b>	<b>100.0</b>	<b>14,837</b>	<b>100.0</b>	<b>32,700</b>	<b>45.4</b>
Pharmaceutical products segment	30,543	96.8	14,293	96.3	—	—
Generics, proprietary products and new drugs	26,148	82.9	11,815	79.6	25,870	45.7
Diagnostics	2,780	8.8	1,817	12.3	4,500	40.4
Others segment	1,015	3.2	544	3.7	—	—
<b>Cost of sales</b>	<b>23,374</b>	<b>74.1</b>	<b>11,204</b>	<b>75.5</b>	—	—
<b>SG&amp;A expenses</b>	<b>8,425</b>	<b>26.7</b>	<b>3,931</b>	<b>26.5</b>	—	—
R&D expenses	2,419	7.7	1,006	6.8	2,820	35.7
<b>Operating profit/loss</b>	<b>(241)</b>	—	<b>(298)</b>	—	<b>200</b>	—
<b>Ordinary profit</b>	<b>58</b>	<b>0.2</b>	<b>10</b>	<b>0.1</b>	<b>100</b>	<b>10.6</b>
<b>Net profit attributable to owners of parent</b>	<b>339</b>	<b>1.1</b>	<b>31</b>	<b>0.2</b>	<b>60</b>	<b>52.5</b>

# Pharmaceutical Sales to Year-on-Year

## Generics, Proprietary Products and New Drugs

(¥mn)

	FY2022			FY2023			
	2Q Amount	% of Sales	Full Year Amount	2Q Amount	% of Sales	2Q Change	YOY (%)
<b>Total</b>	<b>13,695</b>	<b>100.0</b>	<b>26,148</b>	<b>11,815</b>	<b>100.0</b>	<b>(1,880)</b>	<b>(13.7)</b>
Generics	13,010	95.0	24,803	11,146	94.3	(1,863)	(14.3)
To medical institutions	12,423	—	23,698	10,736	—	(1,686)	(13.6)
To other makers*	586	—	1,105	409	—	(177)	(30.2)
Proprietary products and new drugs	685	5.0	1,345	668	5.7	(16)	(2.4)
Uralyt	291	—	575	282	—	(8)	(2.9)
Others	394	—	769	385	—	(8)	(2.1)

## Chemiphar, ODM Generics

<b>Total</b>	<b>13,627</b>	<b>—</b>	<b>25,881</b>	<b>11,559</b>	<b>—</b>	<b>(2,067)</b>	<b>(15.2)</b>
Generics (ODM)	617	—	1,078	412	—	(204)	(33.1)

\* Includes exports.

# Pharmaceutical Sales to Full Year Forecasts

## Generics, Proprietary Products and New Drugs

(¥mn)

	FY2022		FY2023			
	Full Year Amount	% of Sales	2Q Amount	% of Sales	Full Year Forecasts	Progress Rate (%)
<b>Total</b>	<b>26,148</b>	<b>100.0</b>	<b>11,815</b>	<b>100.0</b>	<b>25,870</b>	<b>45.7</b>
Generics	24,803	94.9	11,146	94.3	24,640	45.2
To medical institutions	23,698	—	10,736	—	23,830	45.1
To other makers*	1,105	—	409	—	810	50.6
Proprietary products and new drugs	1,345	5.1	668	5.7	1,230	54.4
Uralyt	575	—	282	—	530	53.4
Others	769	—	385	—	700	55.1
<b>Chemiphar, ODM Generics</b>						
<b>Total</b>	<b>25,881</b>	<b>—</b>	<b>11,559</b>	<b>—</b>	<b>25,670</b>	<b>45.0</b>
Generics (ODM)	1,078	—	412	—	1,030	40.1



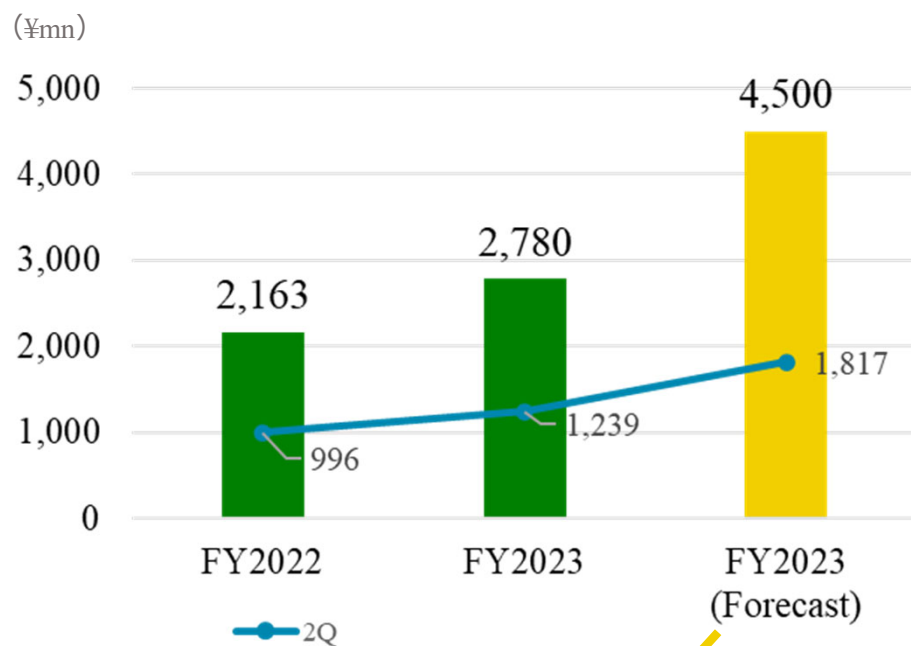
# Sales Distribution by Launch Year

(¥mn)

	FY2022		FY2023			Product Lineup
	2Q Amount	Distrib. (%)	2Q Amount	Distrib. (%)	YOY (%)	
FY2019 and before	11,977	92.1	9,824	88.1	(18.0)	
FY2020	688	5.3	550	4.9	(20.1)	▪ Memantine ▪ Celecoxib
FY2021	224	1.7	201	1.8	(10.3)	▪ Eszopiclone ▪ Duloxetine
FY2022	118	0.9	500	4.5	321.3	▪ Febuxostat ▪ Esomeprazole
FY2023	—	—	68	0.6	—	▪ Azilsartan
<b>Total</b>	<b>13,010</b>	<b>100.0</b>	<b>11,146</b>	<b>100.0</b>	<b>(14.3)</b>	

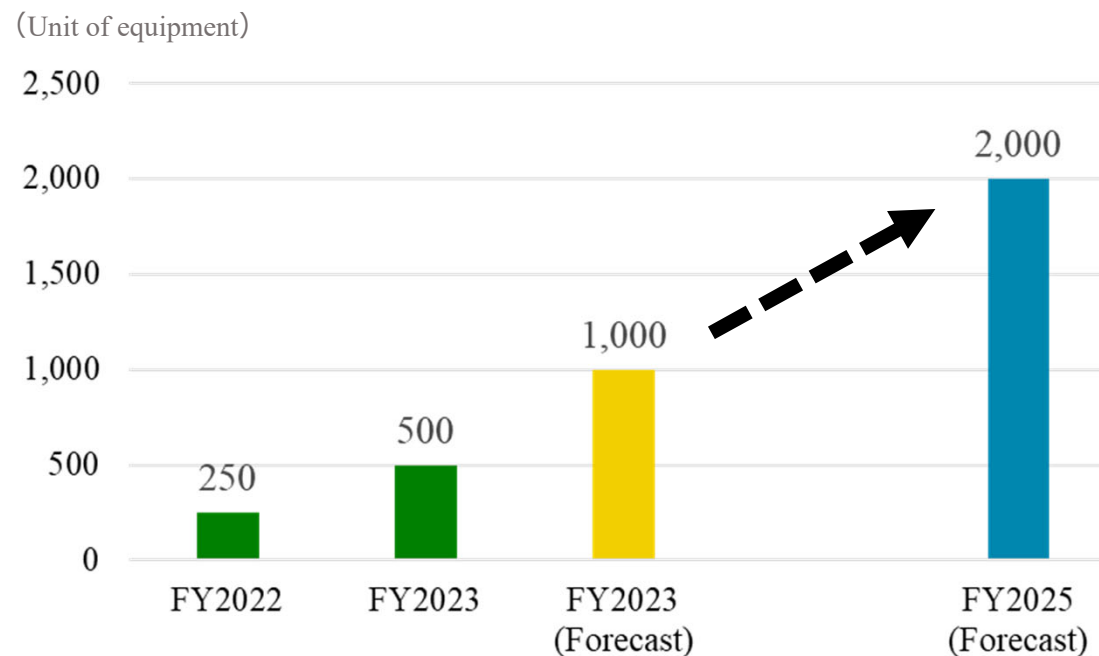
# Sales of Diagnostics

## ■ Sales of Diagnostics



Sales of 2Q FY2023: ¥1,817 million  
(46.7% YOY, 40.4% to forecast)

## ■ Domestic target of DropScreen



At the end of September 2023:  
800 units

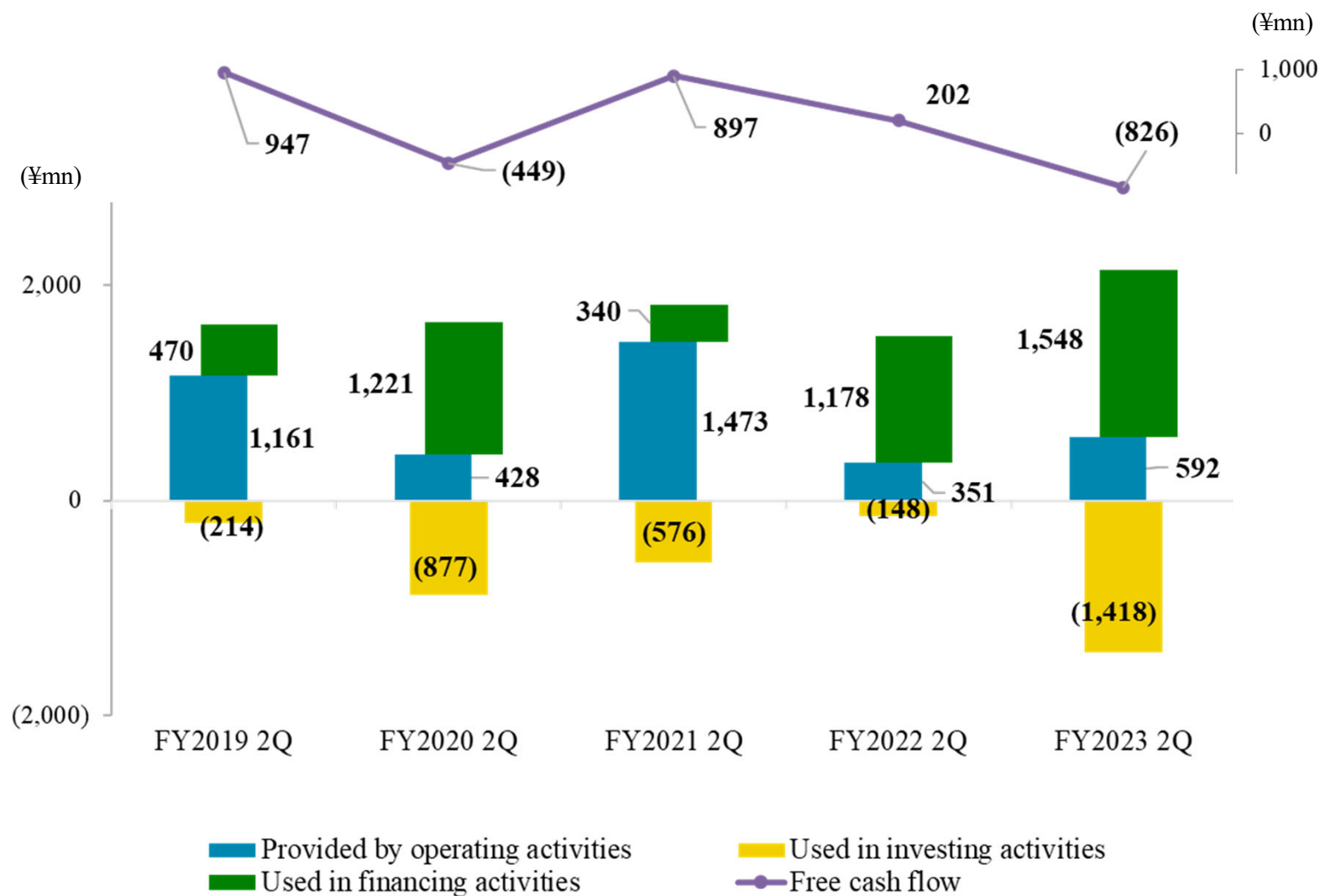
# Balance Sheet

(¥mn)

	FY2022	FY2023				
	March 31, 2023	Sept. 30, 2023	Change	Reason for changes		
Current assets	33,436	34,677	1,240	Cash and deposits	791	*
				Notes and accounts receivable—trade, and	(412)	
				Inventories	1,124	For increased production
				Construction in progress	1,161	*
Non-current assets	15,134	16,193	1,058	Investment securities	248	
Total assets	48,571	50,870	2,298			
Current liabilities	14,766	14,829	62	Purchase payables	(72)	
				Current portion of long-term borrowings	116	
Non-current liabilities	15,270	17,492	2,222	Long-term borrowings	1,616	*
Total net assets	18,534	18,548	13			
Total liabilities and net assets	48,571	50,870	2,298			

\* Additional installation at Building No. 3 of our Tsukuba Factory.

# Cash Flow



# Expenditure and Per Share Information

## Capital Expenditure and Other

(¥mn)

	FY2022		FY2023			
	2Q Amount	Full Year Amount	2Q Amount	YOY (%)	Full Year (Forecast)	Usage Rate (%)
Capital expenditure	299	573	1,301	334.8	3,700	35.2
Depreciation and amortization	737	1,500	715	(2.9)	1,450	49.4

Note to expenditure: We are budgeting for total capital expenditure of ¥3,700 million as we envision additional installation at Building No. 3 of our Tsukuba Factory to meet the need for increased production.

## Per Share Information

(¥)

	FY2022		FY2023		
	2Q Amount	Full Year Amount	2Q Amount	Change	Full Year (Forecast)
Earnings per share	248.43	94.07	8.72	(239.71)	16.62
	Sept. 30, 2022	March 31, 2023	Sept. 30, 2023	Change	Full Year (Forecast)
Book value per share	5,252.48	5,130.65	5,139.65	(112.83)	—
Dividends per share	0.00	50.00	0.00	0.00	50.00
Dividend payout ratio (%)	—	53.2	—	—	300.8

# Indexes

	FY2019	FY2020	FY2021	FY2022	2Q FY2023
Cost of sales ratio (%)	60.5	63.7	72.1	74.1	75.5
SG&A Expense to sales ratio (%)	38.4	34.5	25.4	26.7	26.5
Operating profit to sales ratio (%)	1.1	1.8	2.5	—	—
R&D expenses to sales ratio (%)	6.8	6.3	7.4	7.7	6.8
EBITDA (millions of yen)	1,704	2,099	2,727	1,682	795
Current ratio (x)	2.13x	2.16x	2.00x	2.26x	2.34x
Debt-to-equity ratio (%)	85.2	84.0	78.9	81.0	90.4
Equity ratio (%)	37.9	38.2	37.4	38.1	36.5
Return on equity (%)	2.5	2.8	3.8	1.8	0.2
Net income ratio (%)	1.4	1.6	2.2	1.1	0.2
Total asset turnover (%)	68.4	67.8	67.3	64.4	29.8
Financial leverage (%)	267.1	258.3	261.2	264.7	268.1
Dividend payout ratio (%)	41.2	36.3	25.7	53.2	—

# Three Plus 1 Principal Goals

We striving to increase our capacity to generate earnings through generic drugs and diagnostics and expand our business domains by leveraging alkalizers and new drugs. Further, we intend to strengthen our overseas activities to maximize our corporate value and achieve sustainable growth.



# Roadmap

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

Goal	Activity	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Diagnostics	Expand sales of DropScreen	Expand domestic market. / Target of installation: 2,000 in FY2025. / Aim to achieve continuous business expansion through creating new series of measuring reagents.									
		Sequential launch in Europe, the Americas and Asia.									
		Create new version of equipment for domestic market and additional reagents for abroad.									
Alkalizer	DFP-14323: Develop anti cancer agent	Phase 1/2 for pancreatic cancer	Evaluation and preparation./ 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.					Application, approval and launching	
Drug discovery	NC-2800: Conduct phase 1 and 2a trials; out-license	Agreements with Sumitomo Pharma	Conduct phase 1 and 2a trials in accordance with AMED's CiCLE program						Licensee company will conduct phase 2b and 3 trials.		
	NC-2500: Out licencing activity by additional indications		Licensee company is developing in China as a treatment for hyperuricemia and gout.					Continue licencing activity by another indication.			
	NC-2600: Out licencing activity by additional indications.					Realize licencing out targeting chronic cough and contribution to earnings through milestones.					
	DFP-14323: Develop anti cancer agent	Conduct phase 2		Evaluation and preparation./ Phase 3				Application, approval and launching			
	Discover new compounds by utilizing AI	Searching for and identifying targets, optimize new compound.					Preclinical phase/ License out	Discovery of new compounds through the application of new methods.			
Overseas business	From export to local development and production	ASEAN and China: Sell eleven products to four countries until FY2025.					Ongoing efforts aimed at expanding our product lineup and the number of countries in which these products are sold.				
		Middle East and Africa: Multipul application for approval until FY2025									



# New drug development: Pipelines

> As of September 2023.



Item	Function (Target)	Pre-clinical	Phase 1	Phase 2	Phase 3
NC-2500	XOR inhibitor (Hyperuricemia, gout)	In-house drug development	In-house drug development	Development by licensees	
NC-2600	P2X4 receptor antagonist (Neuropathic pain, chronic cough)	In-house drug development	In-house drug development		
NC-2700	URAT1 inhibitor (Hyperuricemia, gout)	In-house drug development			
NC-2800	$\delta$ opioid receptor agonist (Depression/Anxiety)	In-house drug development	Development through alliances		
DFP-17729	Cancer microenvironment improving agent (Pancreatic cancer)	Development through alliances	Development through alliances	Development through alliances	
DFP-14323	Anti cancer agent (Non-small cell lung cancer)	Development through alliances	Development through alliances	Development through alliances	
Calvan	$\alpha 1\beta 1$ blocker (Huntington's disease)			Development by licensees	

# Pipelines — In-house Development Pipelines①

## NC-2500 (XOR inhibitor)

Stage	Target	Originator	Licensee
Finished phase 1	Hyperuricemia, gout	Nippon Chemiphar	Nanjing Neiwa Faith Pharmaceutical Co., Ltd.
Feature		Note	
<ul style="list-style-type: none"><li>▪ Suppresses uric acid production by inhibiting XOR.</li><li>▪ We confirmed its unique property to lowers blood uric acid levels gradually in phase 1 trials, suggesting it may rectify acute attack of gout.</li></ul>		<ul style="list-style-type: none"><li>▪ We signed a licensing agreement with Nanjing Neiwa Faith for gout and hyperuricemia in 2023, and preparations are underway to conduct clinical trials in China.</li><li>▪ Preliminary data indicates that NC-2500 is effective against neurodegenerative disorders. We are exploring the possibility of expanding the application of NC-2500 to include such disorders.</li></ul>	

## NC-2600 (P2X4 receptor antagonist)

Stage	Target	Originator	Joint developer
Finished phase 1	Neuropathic pain and chronic cough	Joint research including Chemiphar	N.A.
Feature		Note	
<ul style="list-style-type: none"><li>▪ Has a unique mechanism of action that inhibits P2X4 receptors.</li></ul>		<ul style="list-style-type: none"><li>▪ In vivo tests have confirmed its effectiveness against chronic cough, and we are exploring the drug's potential as a therapeutic agent with a new mechanism without side effects such as loss of taste.</li><li>▪ Conducting out-licensing activities.</li></ul>	

# Pipelines — In-house Development Pipelines②

## NC-2700 (URAT 1 inhibitor)

Stage	Target	Originator	Joint developer
Finished preclinical	Hyperuricemia, gout	Joint research including Chemiphar	—
Feature		Note	
▪ Promotes the excretion of uric acid from the body by inhibiting the transporter URAT 1.		▪ Non-clinical studies have shown that it facilitates the excretion of uric acid but ameliorates aciduria, thereby helping to prevent kidney damage and kidney stones, which are concerns when uric acid is excreted.	

## NC-2800 (Delta opioid receptor agonist)

Stage	Target	Originator	Joint developer
Phase 1	anxiety and depression	Joint research including Chemiphar	Sumitomo Pharma Co., Ltd.
Feature		Note	
▪ The drug targets $\delta$ opioid receptors, and data suggest it has fewer side effects such as dependence, tolerance, constipation, and respiratory depression than opioid $\mu$ receptor agonists like morphine, and strikes an excellent balance between safety and efficacy.		▪ AMED's CiCLE project selected it for public funding and support the development. ▪ Administration will be completed by September 2023 and data will be analyzed.	

# Pipelines — In-licensing Pipelines

## DFP-17729 (Cancer microenvironment improving agent)

Stage	Target	Originator	Developer
Finished phase 2	Pancreatic cancer	Delta-Fly Pharma, Inc. (DFP)	DFP
Feature		Note	
▪ By alkalizing tumor microenvironments, DFP-17729 has been shown to suppress cancer cell activities and facilitate the efficacy of anticancer agents.		▪ In 2020 we concluded a license agreement with DFP and acquired exclusive rights to market in Japan. ▪ Finished phase 2 and data analysis for efficacy and safety is underway to prepare for the next phase of trials. ▪ We expect that DFP-17729 could be launched in FY2026 at the earliest.	

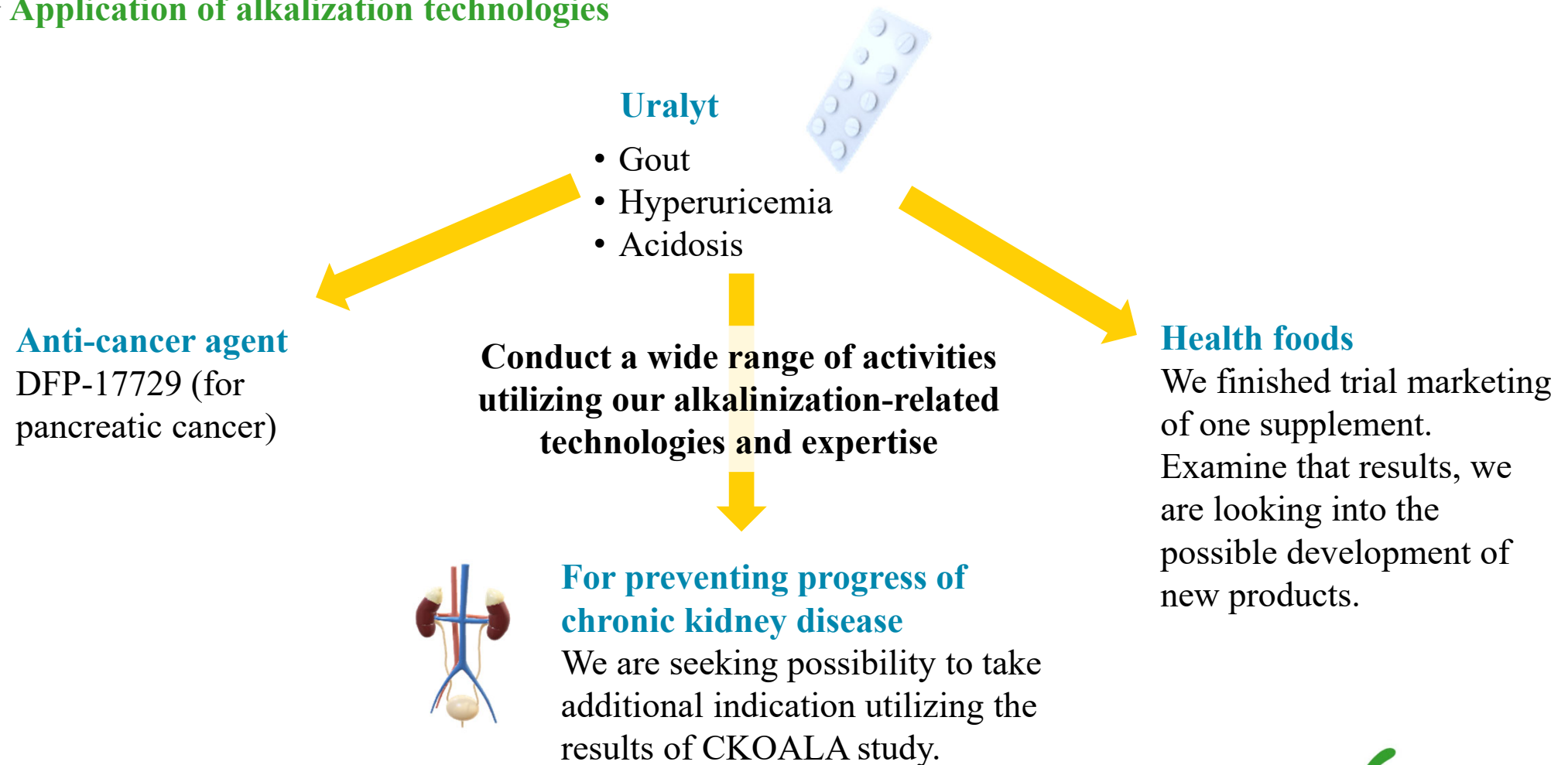
## DFP-14323 (Anti-cancer agent)

Stage	Target	Originator	Developer
Finished phase 2	Non-small cell lung cancer	Delta-Fly Pharma, Inc. (DFP)	DFP
Feature		Note	
▪ Strengthens the immune response of cancer patients by binding to aminopeptidase N. In this way, the substance reduces the dose required of standard anticancer drugs, and enhances their efficacy without increasing the side effects.		▪ In 2022 we concluded a license agreement with DFP and acquired exclusive rights to market in Japan. ▪ The phase 2 results were presented at the American Society of Clinical Oncology meeting held in June 2022. ▪ We expect that DFP-14323 could be launched in FY2027 at the earliest.	

# Multifaceted Development of 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



**We will strongly continue to promote the sales of DropScreen. It facilitates the creation of a new market for in-house allergy testing which mainly outsource traditionally.**

## > Allergy diagnostics market

- In Japan: ¥12 billion
  - Global: ¥280 billion  
(North America is the largest.)
- \*By in-house research



Measuring device A-1

## > Domestic activities

- In June 2023, FUJIFILM Medical Co., Ltd. has started selling DropScreen in partnership.
- From October 2022, we started promoting DropScreen cooperation with our pharmaceutical sales department.
- At the end of FY2022, we recorded installations of over 500 units. We are targeting installations of 2,000 units until FY2025.

## > Activities for overseas

- We are developing it to overseas market and selecting candidate partner companies.

**We currently have approval for seven products in four countries: South Korea, China (including Hong Kong), Thailand and Vietnam. In addition, we have applied for approval for three more products in China and Vietnam. We are looking into marketing our generic drugs in the Middle East and Africa.**

➤ **Enroll our generic drugs to abroad.**

- Nippon Chemiphar Vietnam (NC-VN)'s Rebamipide tablets, which were approved in Vietnam at the end of 2022 received Group 1 status in September 2023, which allows the drug to be sold at the highest drug price under the country's bidding system. In Vietnam, we have several more drug products which have been applied or are in process of apply.
- In China, Epinastine tablets were approved in May 2023. Preparations are underway for release within this fiscal year.
- We conducted market research in the Middle East and Africa using advice from the International Finance Corporation (IFC) of the World Bank Group and its network. We are now arrowing down the scope of countries, partners, and specific products.



IFC officers visited factory of NC-VN

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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.