Nippon Chemiphar Co., Ltd.

（TSE 4539）

Highlights of FY2022 Business Results

(Year ended March 31, 2023)

Chemiphar

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Chemiphar

I. Summary of Results

- FY2022 Business performance
- Sales, Income
- Operating Profit: Forecast vs. Result
- Pharmaceutical Sales
- Balance Sheet
- Cash Flow

FY2022 Business performance

Outline of Results

- **Net sales down 2.9% YOY, achieved 97.1% to forecast.**
  —Although sales of diagnostics exceeded our forecast thanks to strong sales of DropScreen, this was not enough to compensate for the sales decline in pharmaceuticals due to shipment adjustments and the suspension of shipments on certain products in the second half as well as the impact of NHI price revisions.
- **Even though we recorded a consolidated operating loss, we maintained net profitability thanks to foreign exchange gains and gains on the sale of marketable securities.**

Activities

- **Securing production capacity and bolstering sales of DropScreen.**
  —Eliminated the supply bottleneck with new added production capacity for reagents. Commenced promotional support from our pharmaceutical sales department and recorded installations of over 500 units.
- **Progress in New Drug Discovery**
  —Advancing Phase I trials on NC-2800 and completed Phase II trials on DFP-17729 and DFP-14323.
- **Ramped up Production Volume in Generic Pharmaceuticals**
  —Commenced two-shift operations at both domestic and Vietnamese factories and converted to in-house production of certain products.

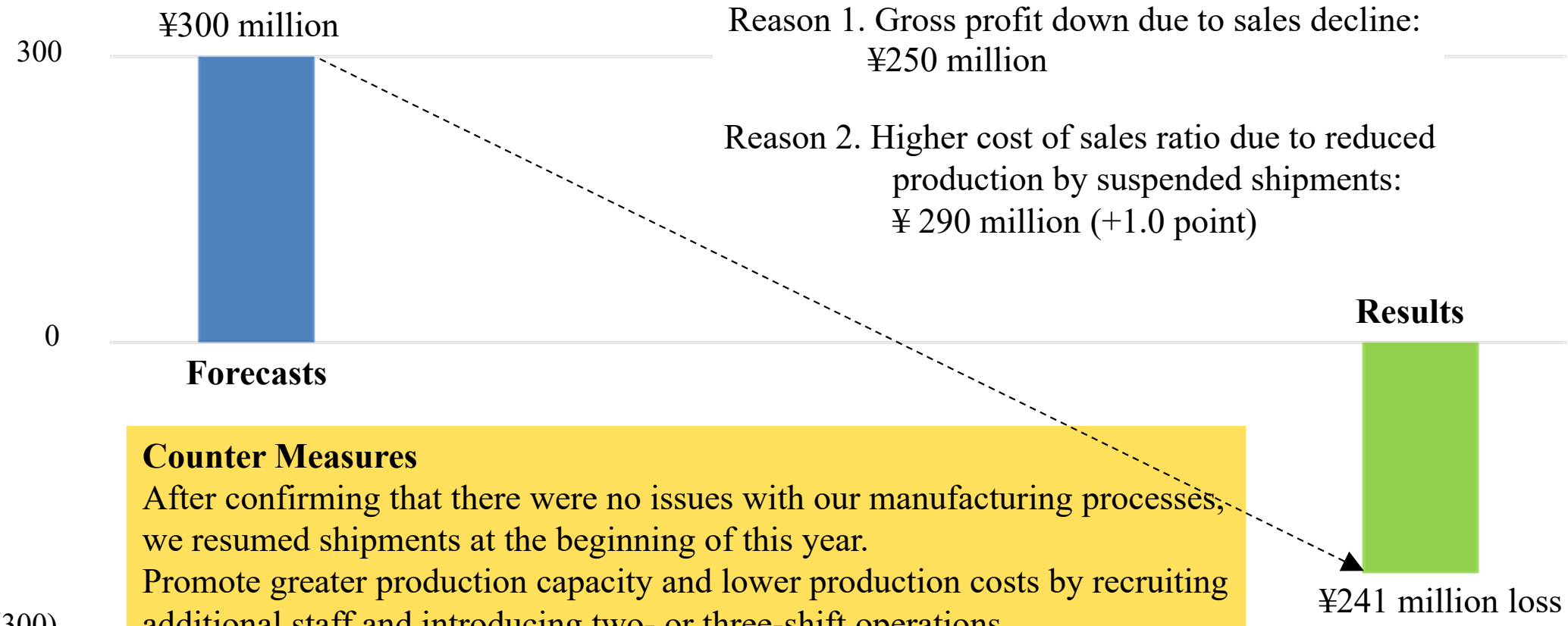
Sales, Income

(¥mn)

	FY2021		FY2022					
	Amount	% of Sales	Amount	% of Sales	YOY Change	YOY %	Full Year (Forecast)	Achieved (%)
Net sales	32,506	100.0	31,559	100.0	(947)	(2.9)	32,500	97.1
Pharmaceuticals	31,501	96.9	30,543	96.8	(958)	(3.0)		
Generics, proprietary products and new drugs	28,037	86.3	26,148	82.9	(1,888)	(6.7)		
Diagnostics	2,163	6.7	2,780	8.8	616	28.5		
Others	1,004	3.1	1,015	3.2	11	1.2		
Cost of sales	23,432	72.1	23,374	74.1	(57)	(0.2)		
YOY				+2.0p				
SG&A expences	8,248	25.4	8,425	26.7	177	2.2		
YOY				+1.3p				
Operating profit or loss	825	2.5	(241)	—	—	—	300	—
Ordinary profit	1,022	3.1	58	0.2	(964)	(94.3)	500	11.7
Net profit attributable to owners of parent	700	2.2	339	1.1	(361)	(51.6)	550	61.7

Operating Profit: Forecast vs. Result

- **Production volumes fell short of our beginning-of-fiscal-year estimates, while declining sales and a rising cost of sales ratio due to suspension of shipments on some products in December 2022 took a heavy toll on operating profit.**



Counter Measures
After confirming that there were no issues with our manufacturing processes, we resumed shipments at the beginning of this year.
Promote greater production capacity and lower production costs by recruiting additional staff and introducing two- or three-shift operations.
→Details are on page 15.

Pharmaceutical Sales

(¥mn)

	FY2021		FY2022				
	Amount	% of Sales	Amount	% of Sales	YOY (%)	Full Year (Forecast)	Achieved (%)
Total(① + ②)	28,037	100.0	26,148	100.0	(6.7)	27,300	95.8
① Generics	26,283	93.7	24,803	94.9	(5.6)	25,870	95.9
To medical institutions	25,043		23,698		(5.4)	24,870	95.3
To other makers	1,239		1,105		(10.8)	1,000	110.5
② Proprietary products and new drugs	1,754	6.3	1,345	5.1	(23.3)	1,430	94.1
Uralyt	623		575		(7.6)	580	99.3
Others	1,131		769		(32.0)	850	90.5
Total(① + ③)	27,139	—	25,881	—	(4.6)	26,880	96.3
③ Generics (ODM)	856	—	1,078	—	25.9	1,010	106.8

Balance Sheet

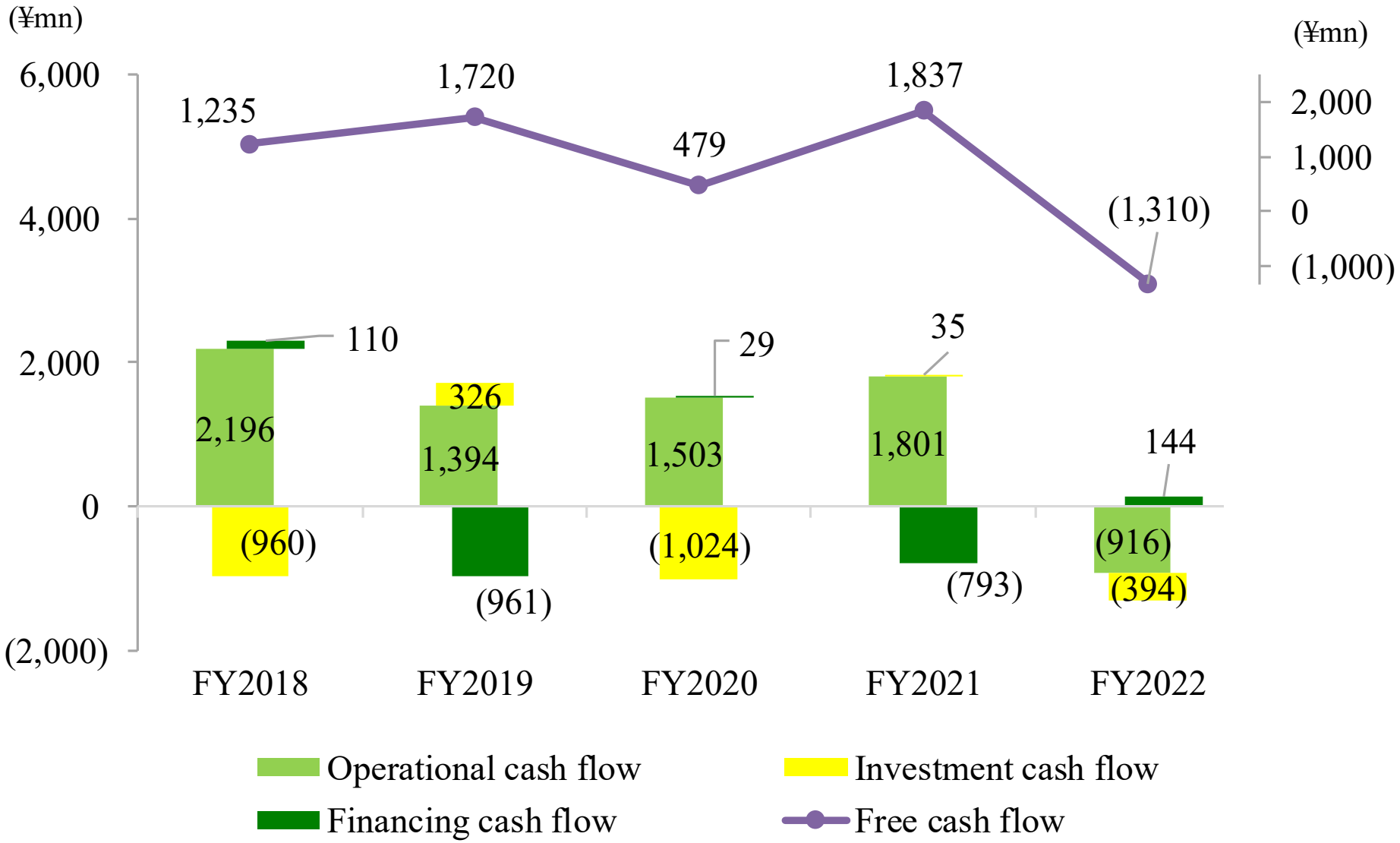
(¥mn)

	March 31, 2022	March 31, 2023	Change
Current assets	33,495	33,436	(58)
Non-current assets	15,957	15,134	(823)
Total assets	49,453	48,571	(882)
Current liabilities	16,750	14,766	(1,983)
Non-current liabilities	14,202	15,270	1,068
Net assets	18,501	18,534	32
Liabilities, net assets	49,453	48,571	(882)

Components	
Cash, deposits	(1,115)
Notes, accounts receivable—trade	(1,390)
Inventories	1,942
Buildings and structures	(185)
Investments in securities	(425)
Accounts payable—trade	(621)
Short-term loans payable	61
Accured expenses	(272)
Long-term loans payable	551

	March 31, 2022	March 31, 2022	Change
Current ratio (x)	2.00	2.26	0.26
Capital-to-asset ratio (%)	37.4%	38.1%	0.7

Cash Flow


(¥mn)
6,000
4,000
2,000
0
(2,000)
(¥mn)
2,000
1,000
0
(1,000)
1,235
1,720
479
1,837
(1,310)
110
29
35
144
2,196
326
1,394
1,503
1,801
(960)
(961)
(1,024)
(793)
(916)
(394)
FY2018
FY2019
FY2020
FY2021
FY2022
Operational cash flow
Investment cash flow
Financing cash flow
Free cash flow

II. FY2023 Forecasts

- Sales, Income
- Pharmaceutical Sales

Sales, Income

(¥mn)

	FY2022		FY2023 Forecasts		
	Amount	% of Sales	Amount	% of Sales	YOY (%)
Net sales	31,559	100.0	32,700	100.0	3.6
Pharmaceuticals	30,543	96.8	—	—	—
Generics, proprietary products and new drugs	26,148	82.9	25,870	79.1	(1.1)
Diagnostics	2,780	8.8	4,500	13.8	61.8
Others	1,015	3.2	—	—	—
Operating profit or loss	(241)	—	200	0.6	—
Ordinary profit	58	0.2	100	0.3	70.4
Net profit attributable to owners of parent	339	1.1	60	0.2	(82.3)

(¥mn)

	FY2022	FY2023 Forecasts	YOY (%)
R&D Expenses	2,419	2,820	16.6
Capital expenditure	573	3,700	x6.5
Depreciation and amortization	1,500	1,450	(3.4)

Pharmaceutical Sales

(¥mn)

	FY2022		FY2023 Forecasts		
	Amount	% of Sales	Amount	% of Sales	YOY (%)
Total(① + ②)	26,148	100.0	25,870	100.0	(1.1)
① Generics	24,803	94.9	24,640	95.2	(0.7)
To medical institutions	23,698		23,830		0.6
To other makers	1,105		810		(26.7)
② Proprietary products and new drugs	1,345	5.1	1,230	4.8	(8.6)
Uralyt	575		530		(7.9)
Others	769		700		(9.0)
Total(① + ③)	25,881	—	25,670	—	(0.8)
③ Generics (ODM)	1,078	—	1,030	—	(4.5)

Chemiphar

III. Management Strategy

- Three Plus 1 Principal Goals
- Roadmap
- Generic Drugs
- Diagnostics
- DropScreen
- Multifaceted Development of Alkalizer
- Expand Alkalizers to Cancer (DFP-17729)
- Expand Alkalizers to CKD
- New drug development: Pipelines
- New drug development: NC-2500 and NC-2600
- New drug development：NC-2800
- New drug development：DFP-14323
- Oversea Business

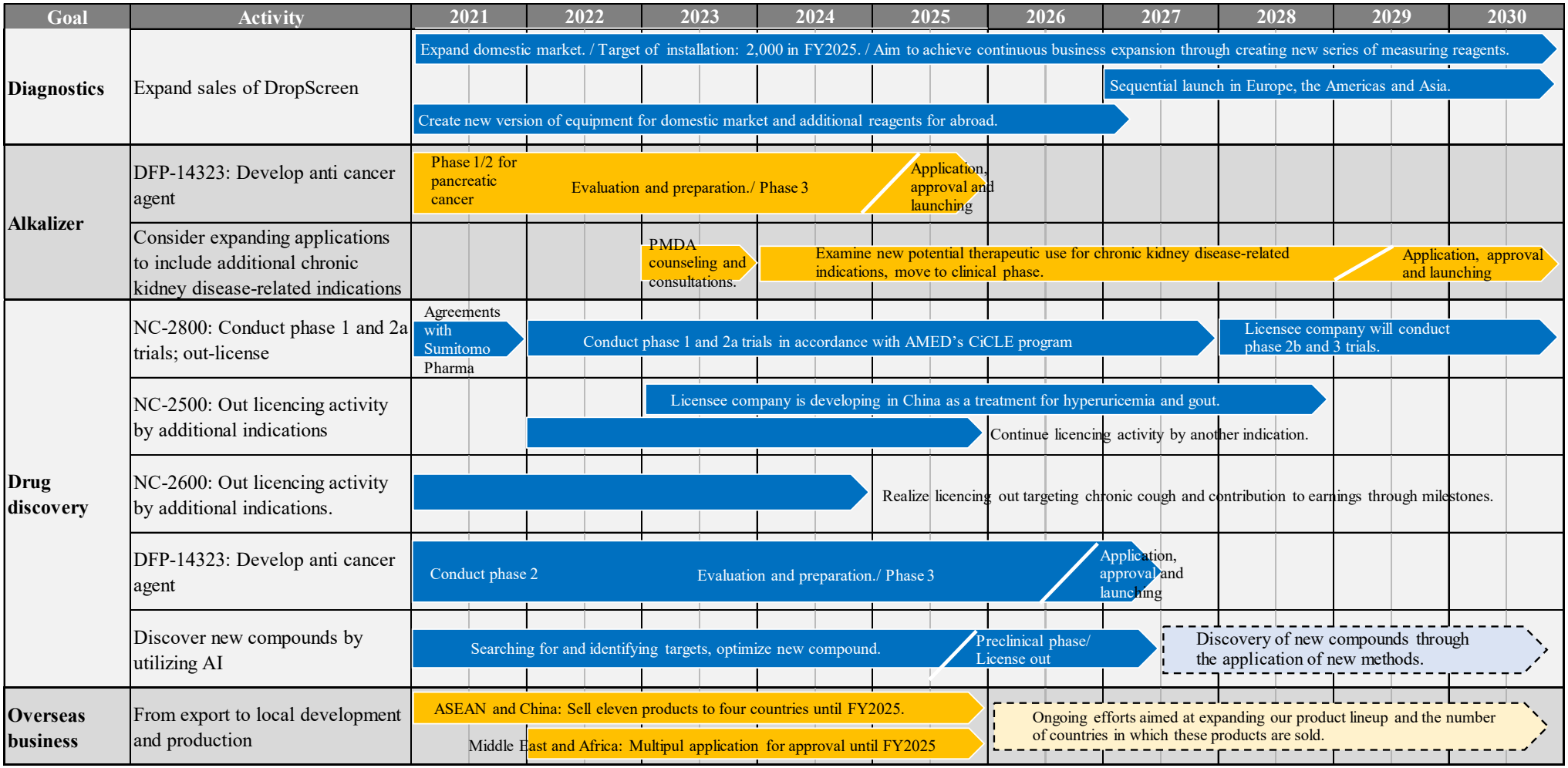
Three Plus 1 Principal Goals

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.

Mission 1	**Generics**	Put quality first and strengthen our earnings structure by added value and improved efficiency.
	Diagnostics	Roll out our allergy measurement reagent technologies in Japan and abroad to maximize revenue.
Mission 2	**Alkalizers**	Ensure multifaceted application of our expertise regarding alkalization therapy.
Mission 3	**Drug discovery**	Roll out our unique drugs on a global scale through in-house drug discovery and in-licensing.
Plus 1	**Overseas Business**	Apply our three goals to overseas markets and target sustainable growth.

Roadmap

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



Generic Drugs

With strengthening our quality assurance system and maintaining competitiveness by steadily developing value-added drug formulations, we are promoting efficiency throughout our supply chain.

> Strengthening of groupwide quality assurance

Quality Assurance

- We fulfill our fundamental responsibility as a pharmaceutical maker by maintaining our ceaseless efforts targeting a stronger quality assurance system.
- We conduct regular audits 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

> Strengthen Supply Chain of Generic Drug

Development

Value-added Products
- Meeting clinical needs.

Improve likelihood of successful development
- Take on the challenge of developing and manufacturing generic drugs with difficult-to-replicate effects through collaboration with academia, etc.

Procurement

Cutting costs
- Shift to high-quality and affordable APIs.

Securing stable supply
- Having multiple APIs suppliers.

Manufacture

Cutting costs
- Expanding production at the Vietnam factory.

Secure production volume
- By introducing new machines and recruiting additional staff.

Seamless transition from development to actual production

Sales

Supports a diverse range of sales channels
- Utilize diverse range of sales channels within both the Company and its subsidiary NPI.

For effective promotion
- Pursuing faster PDCA cycle by sales force automation system and apply AI technology.

Undertakings at Group factories

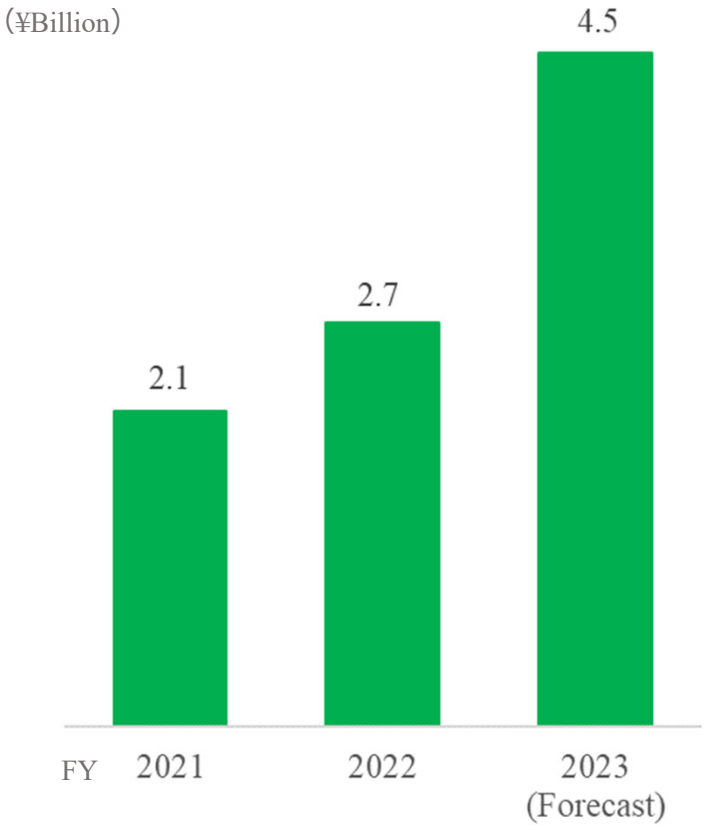
・In Japan: Maintaining two-shift operation (introduced in FY2022) and introducing three-shift operation and recruiting additional staff.

・Vietnam Factory: Introduced two-shift operations in FY2022. In FY2023, plan to shift currently outsourced products to in-house production at our Vietnam Factory.

Diagnostics

Sales of DropScreen have been steadily growing. We will accelerate the expansion both in Japan and overseas and make diagnostic business to a pillar of the Group's earnings.

> Sales of Diagnostics



> Main Products

For Allergy

DropScreen™

・We released in February 2020. It realize screening for 41 allergens in just 30 minutes using only a single drop of blood.

Compact design and water supply and drainage equipment unnecessary.

DP3000 and IgE NC

・90 tests can be conducted simultaneously and the results produced all in only 39 minutes.

Diabetes

HLC-723®GR01

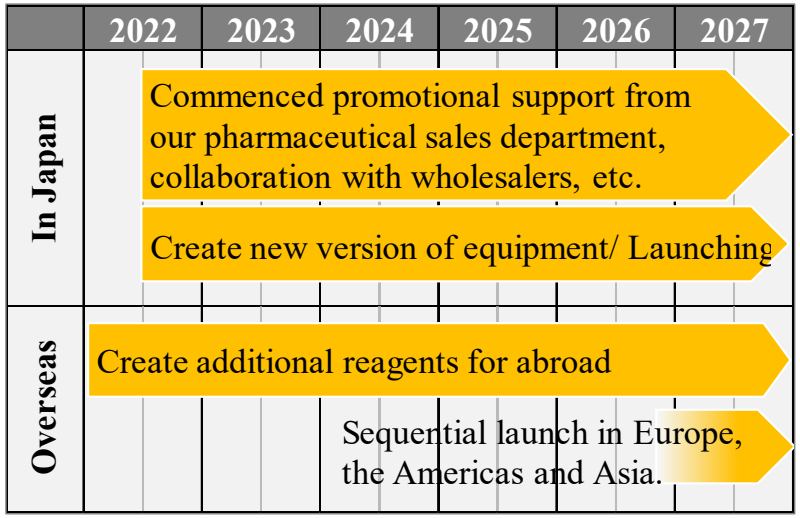
・New model of hemoglobin analyzing device created by Tosoh Corporation. Launched in September 2022.

Chemiphar

DropScreen

We will promote the installation of DropScreen through the cooperation with our pharmaceutical sales department and the Fujifilm Group. Addition to it, now we are developing it to overseas market and selecting candidate partner companies.

> Schedule



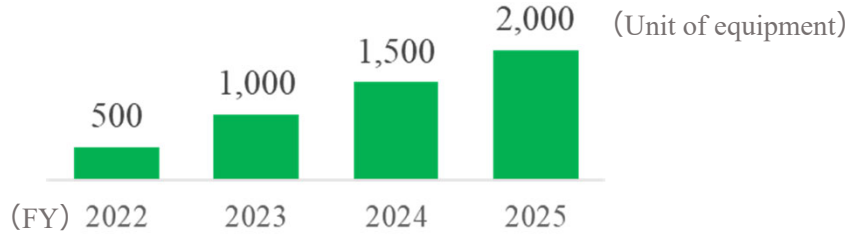
> Allergy diagnostics market

- In Japan: ¥12 billion
- Global: ¥280 billion

  (North America is the largest.)

*By in-house research

> Domestic target of DropScreen



- To facilitate the creation of a new market for in-house allergy testing which mainly outsource traditionally.
- At the end of FY2022, we recorded installations of over 500 units. We are targeting installations of 2,000 units until FY2025.

Multifaceted Development of Alkalizer

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

> Application of alkalization technologies

Uralyt

- Gout
- Hyperuricemi
- Acidosis

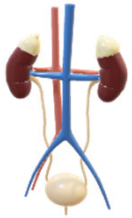
Conduct a wide range of activities utilizing our alkalinization-related technologies and expertise

Anti-cancer agent

DFP-17729 (for pancreatic cancer)

Health foods

We finished trial marketing of one supplement. Examine that results, we are looking into the possible development of new products.



For preventing progress of chronic kidney disease

We are seeking possibility to take additional indication utilizing the results of CKOALA study.

Expand Alkalizers to Cancer (DFP-17729—①)

DFP-17729 is the world's first alkalization therapy with cancer as an indication and is currently being developed for therapeutic use in the treatment of pancreatic cancer patients, which are growing in number.

＞Outline of DFP-17729

- DFP-17729 is expected to generate groundbreaking therapeutic effects combine with various anticancer agents.
- Non-clinical study* indicated anticancer effects when administered in combination with standard anticancer agents.
- In March 2020, we concluded a license agreement with Delta-Fly Pharma, Inc. and acquire exclusive marketing and manufacturing rights in Japan.
- 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.

*Fore further information, please refer to news releaseof Delta-Fly Fharma inc on March 8, 2022

Expand Alkalizers to Cancer (DFP-17729—②)

Finished Phase 2 and under analyzing for next phase. DFP plan to start the next phase during FY2023. We are expected to launch it as early as FY2026.

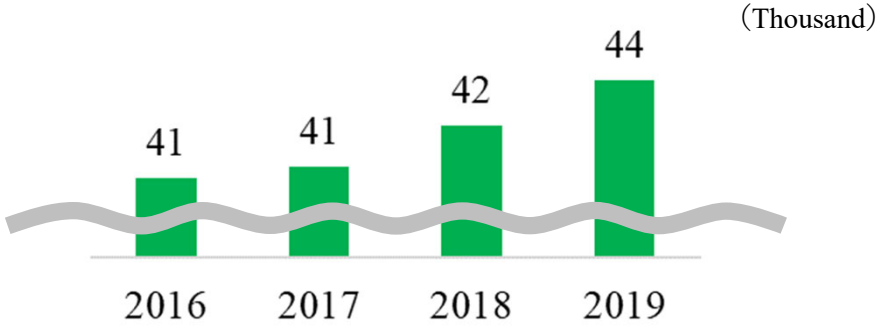
> Schedule

2021	2022	2023	2024	2025	2026
Phase 1/2 for pancreatic cancer	Evaluation and preparation./ Phase 3			Application, approval and launching	

> Number of patients

- About 40,000 patients per year are registered as pancreatic cancer which is the target of DFP-17729.

Number of pancreatic cancer



Source :CANCER STATISTICS IN JAPAN ─ 2022, Foundation for Promotion of Cancer Research

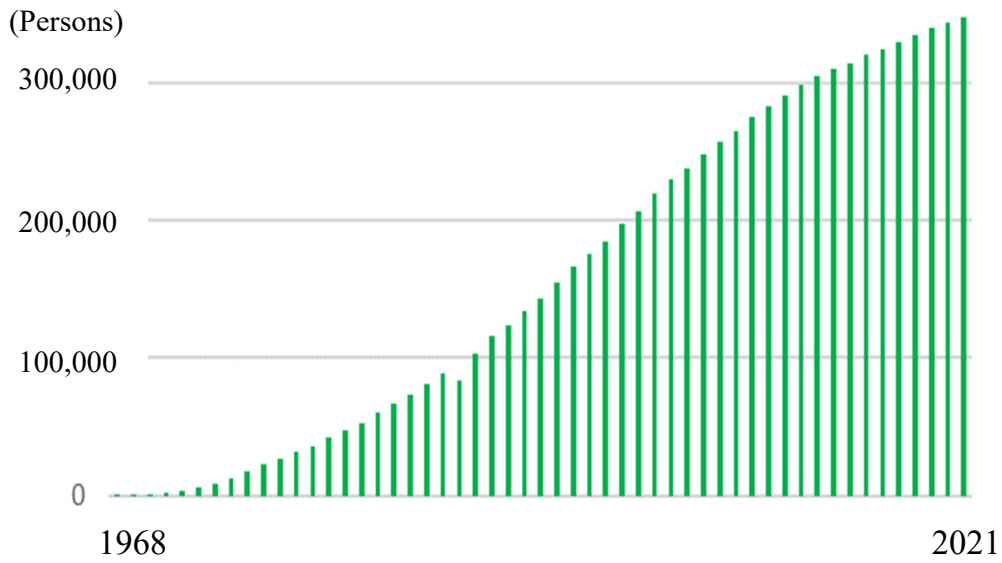
Expand Alkalizers to CKD

We are striving to develop uses for our alkalinization technologies in treatments that inhibit the progression of chronic kidney disease (CKD) .

> 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 social issues.
- We are supporting a CKOALA study underway at Tohoku University concerning the renoprotective effects of oral alkalizers in patients of chronic kidney disease.
- The principal investigator is currently in the process of writing a paper on the results obtained.
- Based on this analysis, we are considering a variety of development possibilities targeting CKD.

Trends in the prevalent dialysis patient count



Source :Annual dialysis data report 2020, the Japanese Society for Dialysis Therapy

New drug development: Pipelines

Addition to our venture-like drug discovery research, we have been pursuing alliances with companies and research institutions that are conducting cutting-edge research in their respective fields.

> As of March 2023.

In-house drug development

Other companies or physician-initiated development

Development with other companies

Item	Function (Target)	Pre-clinical	Phase 1	Phase 2	Phase 3	Notes
NC-2400	PPAR-δ agonist (Lipid metabolism abnormalities)					・Finished Phase 1. ・Licensed to Abionyx Pharma SA (France).
NC-2500	XOR inhibitor (Hyperuricemia, gout)					・**From Februaly 2023, licensee company is developing in China as a treatment for hyperuricemia and gout.** ・Explored possibilities for applications as a treatment for neurodegenerative diseases.
NC-2600	P2X4 receptor antagonist (Neuropathic pain, chronic cough)					・Phase 1 has ended and we are conducting licensing-out activities. ・Began out-licensing for application as a treatment for chronic cough.
NC-2700	URAT1 inhibitor (Hyperuriceia, gout)					・Finished preclinical trial and are conducting licensing-out activities.
NC-2800	δ opioid receptor agonist (Depression/Anxiety)					・Selected by AMED for its funding program on January 2018. ・Concluded a collaborative research and development agreement and an option agreement with Sumitomo Pharma Co., Ltd. and began phase 1.
DFP-17729	Cancer microenvironment improving agent (Pancreatic cancer)					・Acquire exclusive rights to market in Japan from Delta-Fly Pharma, Inc. ・Finished phase 2 and analyzing its data for next phase.
DFP-14323	Anti cancer agent (non-small cell lung cancer)					・Acquire exclusive rights to market in Japan from Delta-Fly Pharma, Inc. ・Finished phase 2 and analyzing its data for preparing phase 3.
Calvan	A1β1 blocker (Huntington's disease)					・Licensed to SOM Biotech SL (Spain). ・Completed the phase 2a trial and presented the data at a conference held in October 2021.

New drug development: NC-2500 and NC-2600

In February 2023, NC-2500 signed a license agreement with a Chinese pharmaceutical company for development in China.
NC-2600 is in negotiations with potential out-licensing companies.

> NC-2500 Outline of license agreement conclusion

- Concluded a licensing agreement with Nanjing Neiwa Faith Pharmaceutical (NF) Co., Ltd., granting NF exclusive rights to develop, manufacture, and sell in the gout and hyperuricemia area in China.
- The number of gout patients in China is expected to increase. In addition, the know-how obtained from NF's development can be expanded to other regions by our company.

> NC-2600 Status of out-licensing activities

- In addition to neuropathic pain, we are developing out-licensing activities targeting chronic cough.
- We are currently negotiating specific out-licensing with overseas companies.

New drug development：NC-2800—①

NC-2800, an opioid delta receptor agonist targeting depression and anxiety, has been adopted by AMED's CiCLE, and is currently being researched and developed in collaboration with Sumitomo Pharma Co., Ltd.

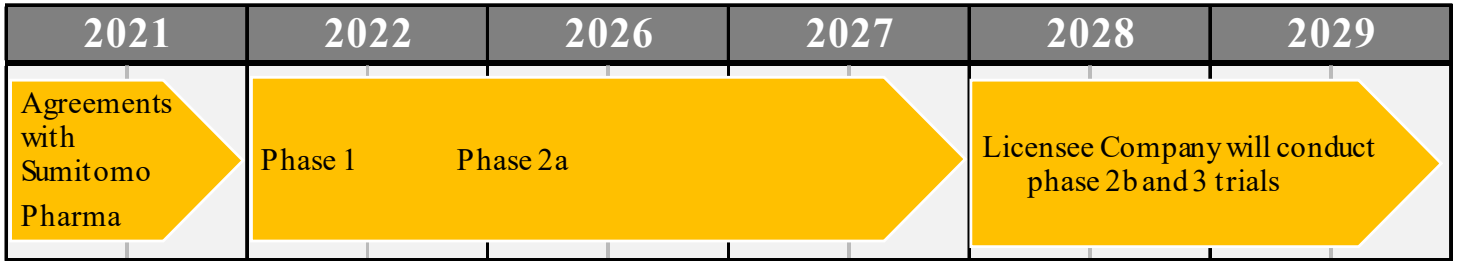
＞Outline of NC-2800

- This drug is characterized that less of the side-effects that these drugs have been known to cause and high levels of safety and efficacy.
- Adopted the CiCLE project which supported by the Japan Agency for Medical Research and Development (AMED) in January 2018.
- Concluded a collaborative research and development agreement and an additional option agreement with Sumitomo Pharma in June 2021. Sumitomo Pharma participated in the CiCLE project as a collaborating institution and will cooperate with Chemiphar to advance the research and development of NC-2800.
- Phase 1 protocol focuses on completing preparations necessary for international clinical studies that begin in phase 2a.
- Patients of mood disorders are increasing in number. However, treatment satisfaction remains below 40%. Expected to be first-in-class due to its high levels of safety and efficacy.

New drug development：NC-2800—②

Phase 2 is currently underway. Phase 2a is scheduled to be completed by around 2027. With the goal of acquiring POC, we will continue to develop with CiCLE.

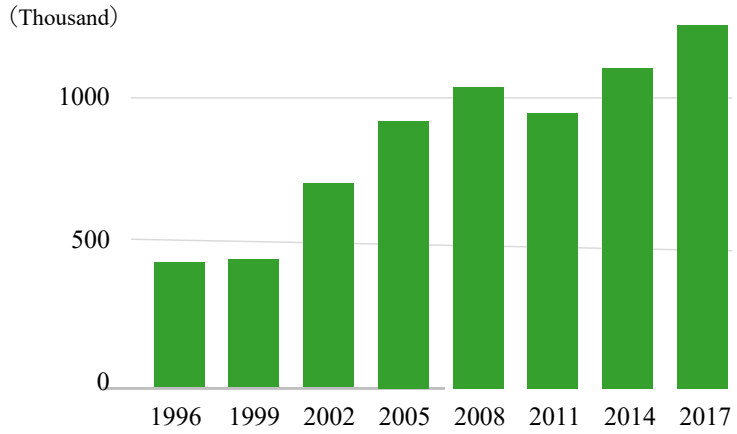
＞Schedule



＞Market

- Annual sales of antidepressants and antianxiety medications are 136 billion yen.

＞Number of patients



- 1.3 million of people per year are diagnosed with mood disorder.

Source :Annual Health, Labour and Welfare Report 2018,

New drug development：DFP-14323—①

DFP-14323 targets lung cancer, which causes more deaths than any cancer affecting other parts of the body and has shown good results in Phase 2.

＞Outline of DFP-14323

- DFP-14323 improves the effectiveness of standard anticancer agents without increasing side effects.
- Chemiphar will market this drug in Japan once approval has been granted.

＞Presentation in ASCO

- At an annual meeting of the American Society of Clinical Oncology Annual Meeting held in June 2022, the results of Phase 2, developed by DFP, were announced.

Final progression-free survival analysis
Combined with afatinib (starting dose of 20 mg/day), DFP-14323 generated a phase 2 median PFS of 23.0 months.

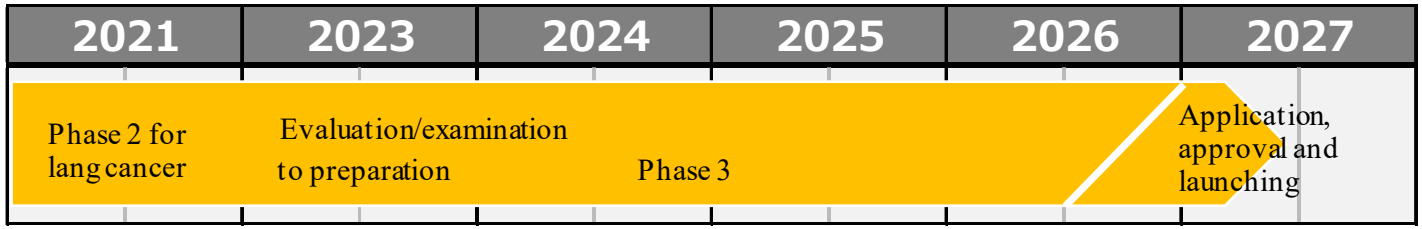
Note: The standard dose of afatinib is 40 mg/day. This trial used a dose reduced by 50%.

(Reference)
A phase 3 study using a 40 mg/day starting dose of afatinib produced a median PFS of 11.1 months.
A phase 3 study using an 80 mg/day starting dose of osimertinib produced a median PFS of 18.9 months.

New drug development：DFP-14323—②

Currently, preparations are underway for Phase 3, and expected to start Phase 3 in fiscal 2023, we may be able to launch the product in 2027 at the earliest.

Schedule

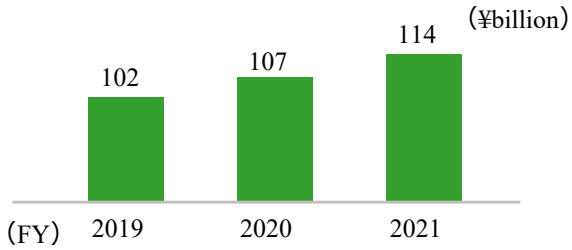


Number of patients

- 120 thousand people per year are diagnosed with lung cancer (including males and females).
- Many of these patients have contracted EGFR mutation-positive lung adenocarcinoma, which is a condition targeted by DFP-14323 (60% of lung cancers are adenocarcinomas, and the frequency of EGFR mutation positivity in adenocarcinoma is 45%).
- This drug has been confirmed to be effective as an add-on to EGFR-TKI, a therapeutic drug for EGFR gene mutation-positive lung cancer.
- **Annual sales of EGFR-TKI in Japan exceed 100 billion yen.**

Market

Annual sales of EGFR tyrosine kinase inhibitors (EGFR-TKIs) in Japan



Oversea Business

We currently have approval for six 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

- In December 2022, we obtained approval in Vietnam for our Rebamipide tablet, which is produced at our Vietnam Factory. Having already been approved in Japan, it is the first oral drug manufactured in Vietnam to be approved in that country.
- We have applied for approval for two products in China, while in July 2022, we applied for the first time in Vietnam for a product with a dosage standard different from that in Japan.
- We conducted market research in the Middle East and Africa, aimed at achieving local sales of generic drugs, with advice from the World Bank Group's International Finance Corporation (IFC) and its network. We are currently narrowing down our list of target countries and partners.

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.