Nippon Chemiphar Co., Ltd.

(TSE 4539)

Highlights of Second Quarter FY2022 Business Results

(Year ending March 31, 2023)

Chemiphar

Contents

Chemiphar

I. Summary of Results

Chemiphar

Sales, Income

(¥mn)

	FY2021		FY2022					
	2Q Amount	% of Sales	2Q Amount	% of Sales	YOY Amount	YOY Change (%)	Full Year (Forecast)	Progress Rate (%)
Net Sales	**15,575**	**100.0**	**16,237**	**100.0**	**662**	**4.3**	**35,000**	**46.4**
Pharmaceuticals	15,115	97.0	15,798	97.3	683	4.5	—	—
Generics, proprietary products and new drugs	13,468	86.5	13,695	84.3	226	1.7	—	—
Diagnostics	996	6.4	1,239	7.6	242	24.3	—	—
Others	460	3.0	439	2.7	(20)	(4.5)	—	—
Cost of sales	**11,265**	**72.3**	**11,976**	**73.8** [+1.5p]	**710**	**6.3**	—	—
SG&A expenses	**4,103**	**26.3**	**4,093**	**25.2** [△1.1p]	**(9)**	**(0.2)**	—	—
Operating profit	**206**	**1.3**	**167**	**1.0**	**(38)**	**(18.8)**	**300**	**55.8**
Ordinary profit	**258**	**1.7**	**752**	**4.6**	**493**	**190.7**	**500**	**150.5**
Net profit attributable to owners of parent	**228**	**1.5**	**896**	**5.5**	**667**	**291.6**	**550**	**163.0**

Pharmaceutical Sales

(¥mn)

	FY2021		FY2022				
	2Q Amount	% of Sales	2Q Amount	% of Sales	YOY (%)	Full Year (Forecast)	Progress Rate (%)
Total (① + ②)	13,468	100.0	13,695	100.0	1.7	29,000	47.2
① Generics	12,581	93.4	13,010	95.0	3.4	27,440	47.4
To medical institutions	12,010		12,423		3.4	26,600	46.7
To other makers	571		586		2.6	840	69.9
② Proprietary products and new drugs	887	6.6	685	5.0	(22.7)	1,560	43.9
Uralyt	317		291		(8.3)	580	50.2
Others	569		394		(30.8)	980	40.2
Total (① + ③)	12,984	—	13,627	—	5.0	28,450	47.9
③ Generics (ODM)	402	—	617	—	53.3	1,010	61.1

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Balance Sheet

(¥mn)

	March 31, 2022	September 30, 2022	Change	Components	
				Cash, deposits	1,516
				Notes, accounts receivable—trade	(1,080)
Current assets	33,495	35,081	1,586	Inventories	1,091
				Buildings and structures	43
Non-current assets	15,957	15,576	(381)	Investments in securities	(567)
Total assets	49,453	50,658	1,204		
				Accounts payable—trade	(168)
				Short-term loans payable	294
Current liabilities	16,750	15,860	(889)	Accured expenses	(201)
Non-current liabilities	14,202	15,822	1,620	Long-term loans payable	1,107
Net assets	18,501	18,974	473		
Liabilities, net assets	49,453	50,658	1,204		

	March 31, 2022	September 30, 2022	Change
Current ratio (x)	2.00	2.21	0.21
Capital-to-asset ratio (%)	37.4	37.4	0.0

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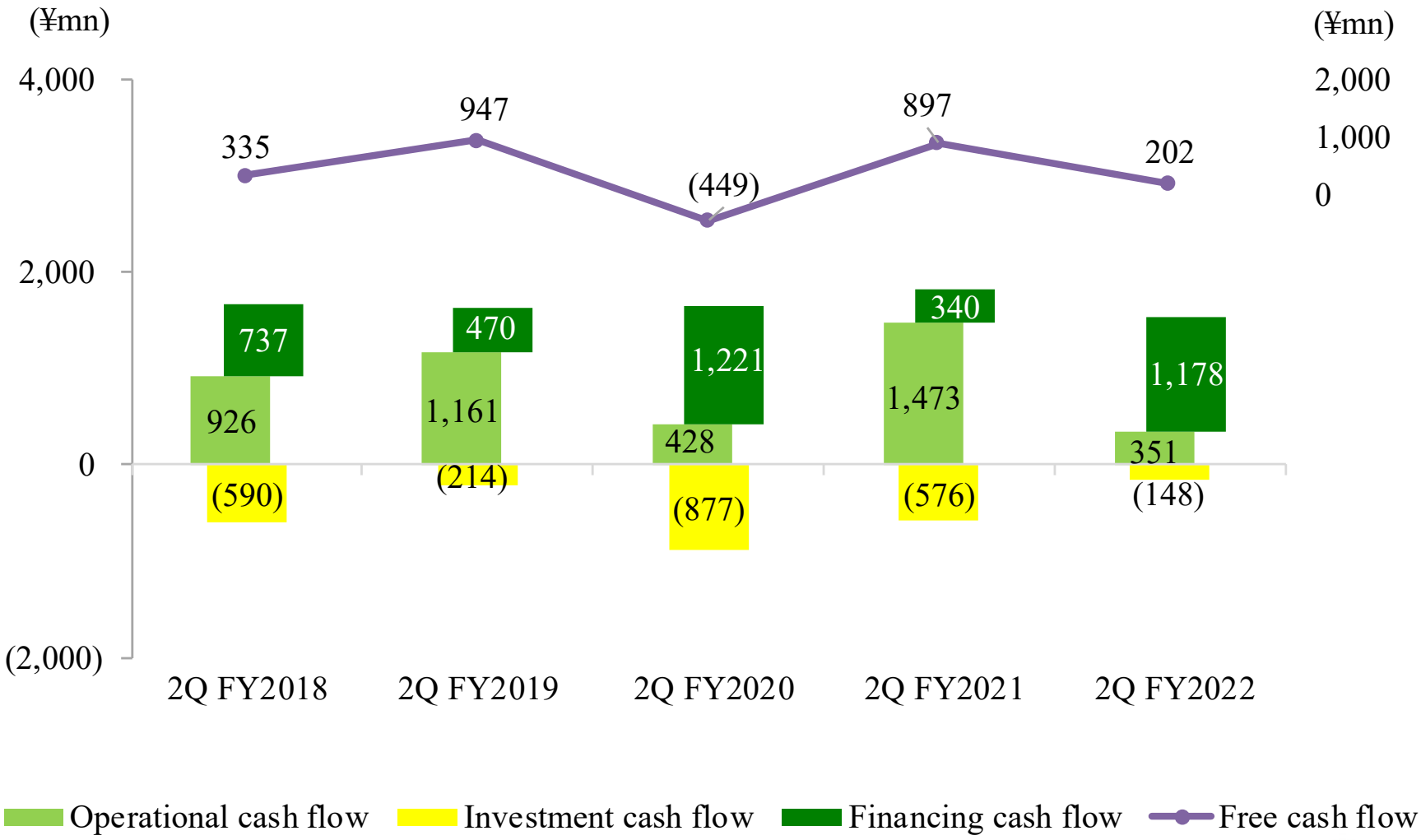
Cash Flow

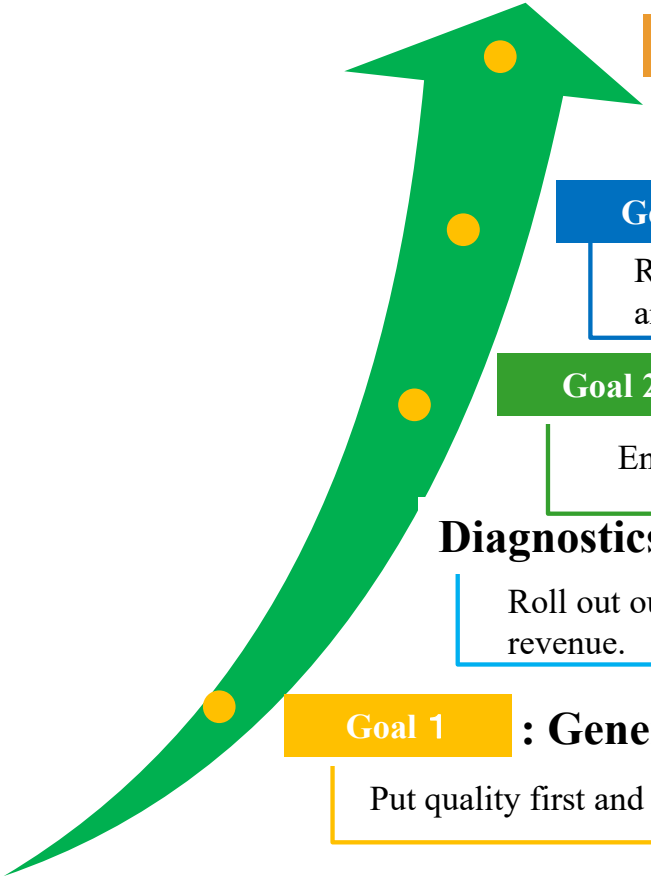

(¥mn)
4,000
2,000
0
(2,000)
(¥mn)
2,000
1,000
0
335
947
(449)
897
202
737
470
1,221
340
1,178
926
1,161
428
1,473
351
(590)
(214)
(877)
(576)
(148)
2Q FY2018
2Q FY2019
2Q FY2020
2Q FY2021
2Q FY2022
Operational cash flow
Investment cash flow
Financing cash flow
Free cash flow

II. Management Strategy

Chemiphar

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.



Plus 1 : Overseas Business

Apply our three goals to overseas markets and target sustainable growth.

Goal 3 : Drug discovery

Roll out our unique drugs on a global scale through in-house drug discovery and in-licensing.

Goal 2 : Alkalizers

Ensure multifaceted application of our expertise regarding alkalization therapy

Diagnostics

Roll out our allergy measurement reagent technologies in Japan and abroad to maximize revenue.

Goal 1 : Generics

Put quality first and strengthen our earnings structure by added value and improved efficiency.

Management Strategy

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
Alkalizer	DFP-17729: anticancer agent	Phase 1/2 for pancreatic cancer		Phase 3		Application, approval					
	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		
	DFP-14323: Develop anti cancer agent	Conduct phase 2			Conduct 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	Sell five products to four countries			Sell 10 products to five countries			Ongoing efforts aimed at expanding our product lineup and the numbe 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	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						

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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.

■Strengthen Generic Drug Business

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.

Cutting costs
Shift to high-quality and affordable APIs.
Securing stable supply
Having multiple APIs suppliers.

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

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.

Development → **Procurement** → **Manufacture** → **Sales**

Quality Assurance

Strengthening of groupwide quality assurance

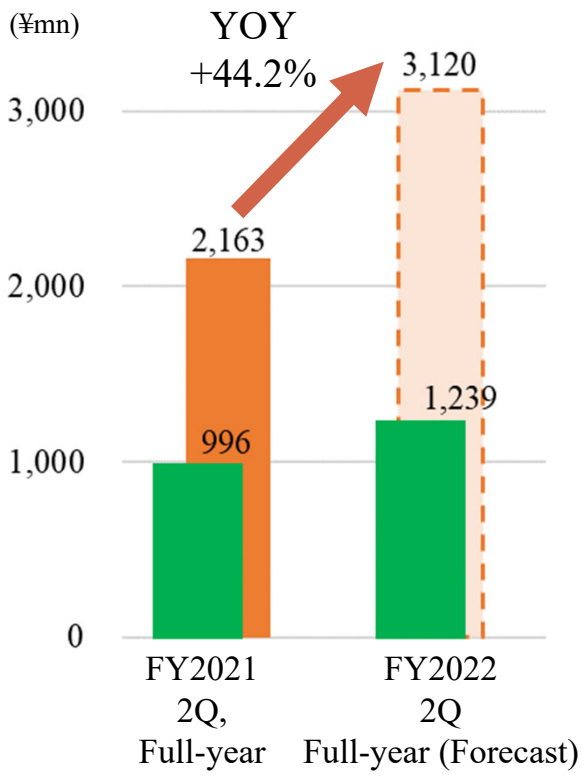
・We fulfill our fundamental responsibility as a pharmaceutical maker by maintaining our ceaseless efforts targeting a stronger quality assurance system.

・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.

Diagnostics

During the second quarter of FY2022, we established an additional production line for DropScreen measuring kits, and our pharmaceutical MRs will begin promoting these kits during the third quarter. We are currently taking concrete action targeting the utilization of these kits overseas.

Sales of Diagnostics



Activities for main Products

DropScreen™

Domestic Market

- To facilitate the creation of a new market for in-house allergy testing which mainly outsource traditionally.
- Our additional measuring kit production line began operating in the second quarter, eliminating a bottleneck that was hindering sales expansion.
- During the third quarter, our pharmaceutical MRs will begin providing promotional support as we aim to achieve 1,000 unit installations within Japan as quickly as possible.

Overseas Market

- We are developing products, ensuring compliance with legal systems, and searching for partners as we aim to expand our business in Europe, the US, and Southeast Asia.

Starting HLC-723GR01 promotion from September 2022.

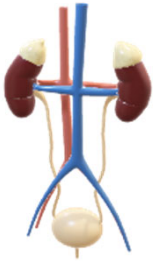
- New model of hemoglobin analyzing device created by Tosoh Corporation.
- Enables more accurate analysis while maintaining the high-speed measurement of the previous model.

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

Anti-cancer agent
DFP-17729 （for pancreatic cancer ）



Seek possibility for preventing progress of chronic kidney disease utilizing the results of CKOALA study

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

Uralyt
- Gout
- Hyperuricemia
- Acidosis

Health foods
In October 2022, we began trial marketing of one supplement and are currently looking into the possible development of new products with fatigue-reducing properties.

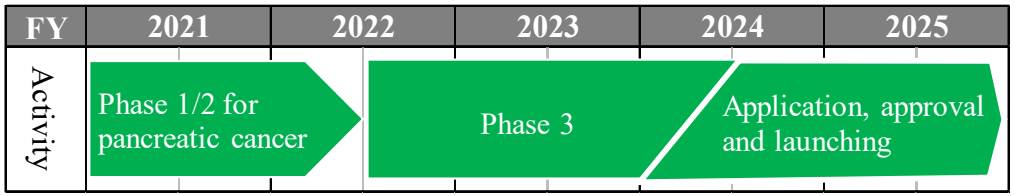
Expand Alkalizers to Cancer (DFP-17729)

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. It also highly promising as a potential therapy for use in the treatment of other types of refractory cancers.

Outline of DFP-17729

- Non-clinical study indicated anticancer effects when administered in combination with standard anticancer agents.
- Concluded a license agreement with Delta-Fly Pharma, Inc.
- Finished phase 2 and analyzing its data for preparing phase 3.

Schedule



Related information

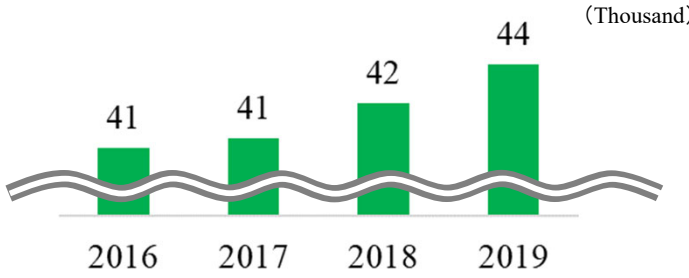
Market

- DFP-17729 is expected to generate groundbreaking therapeutic effects combine with various anticancer agents.

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

- 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.

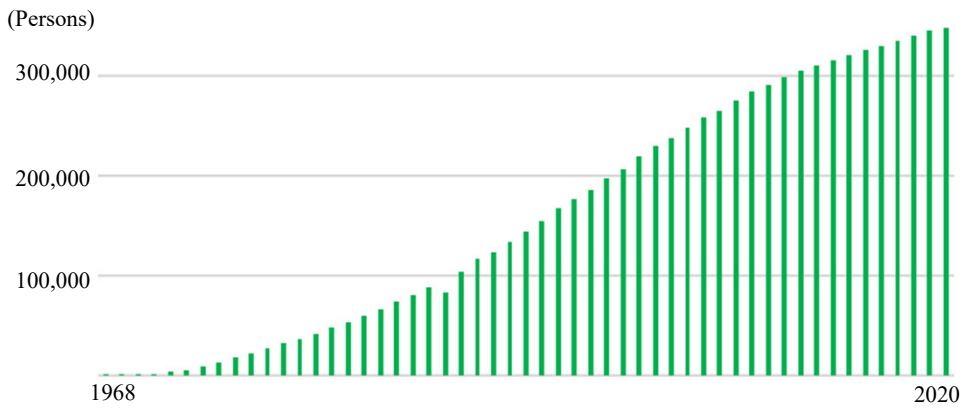
Expand Alkalizers to CKD and Health Food

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

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.
- 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

Investigation for Health Food

- In October 2022, we began trial marketing of our Q enrich supplement, which is prepared using citrate and plant lactobacillus.
- Based on research data and our expertise regarding alkalization therapy, we are also developing functional foods.

Package of Q enrich

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Pipeline

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)					・Phase1has ended and we are conducting licensing-out activities. ・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 preparing phase 3.**
DFP-14323	Anti cancer agent (non-small cell lung cancer)					・Acquire exclusive rights to market in Japan from Delta-Fly Pharma, Inc. **・Phase 2 median PFS values presented at an June 2022 meeting of the American Society of Clinical Oncology.**
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.

As of September 2022.

In-house drug development

Development with other companies

Other companies or physician-initiated development

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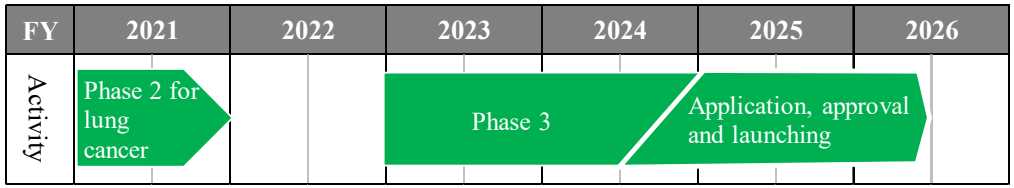
DFP-14323 (Anti Cancer Agent)

DFP-14323 targets lung cancer, which causes more deaths than any cancer affecting other parts of the body. We will aim to generate synergy through our sales activities by handling other oncological drugs in addition to DFP-17729.

Outline of DFP-14323

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

Schedule



Presentation in ASCO

- Delta-Fly Pharma, Inc. presented results of its phase II study regarding DFP-14323 at an annual meeting of the American Society of Clinical Oncology held in June 2022.

Final progression-free survival analysis
Combined with afatinib (starting dose of 20 mg/day), DFP-14323 generated a phase II 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 III study using a 40 mg/day starting dose of afatinib produced a median PFS of 11.1 months.
A phase III study using an 80 mg/day starting dose of osimertinib produced a median PFS of 18.9 months.

Related information

Market	・Annual sales of EGFR tyrosine kinase inhibitors (EGFR-TKIs) in Japan is over 100 billion yen.
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%).

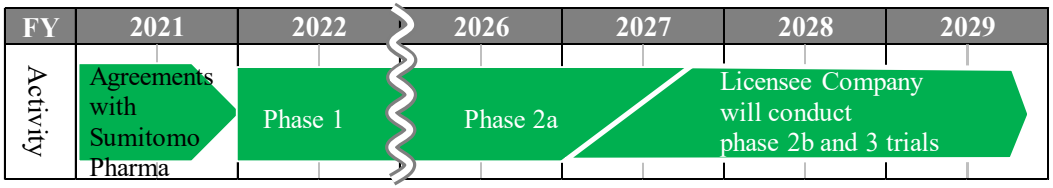
NC-2800 (Delta Opioid Receptor Agonist)

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.

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).
- 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.

Schedule



Related information

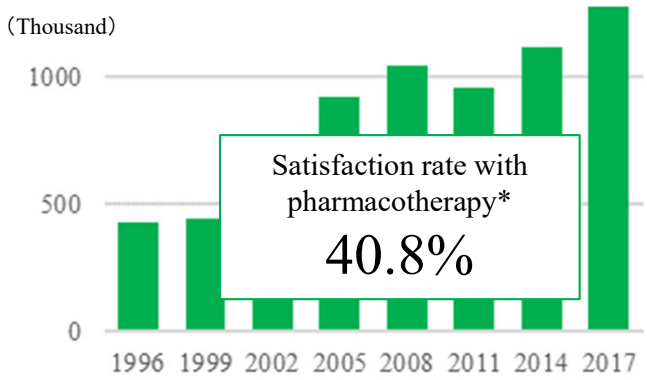
Market

- 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.

Number of mood disorders



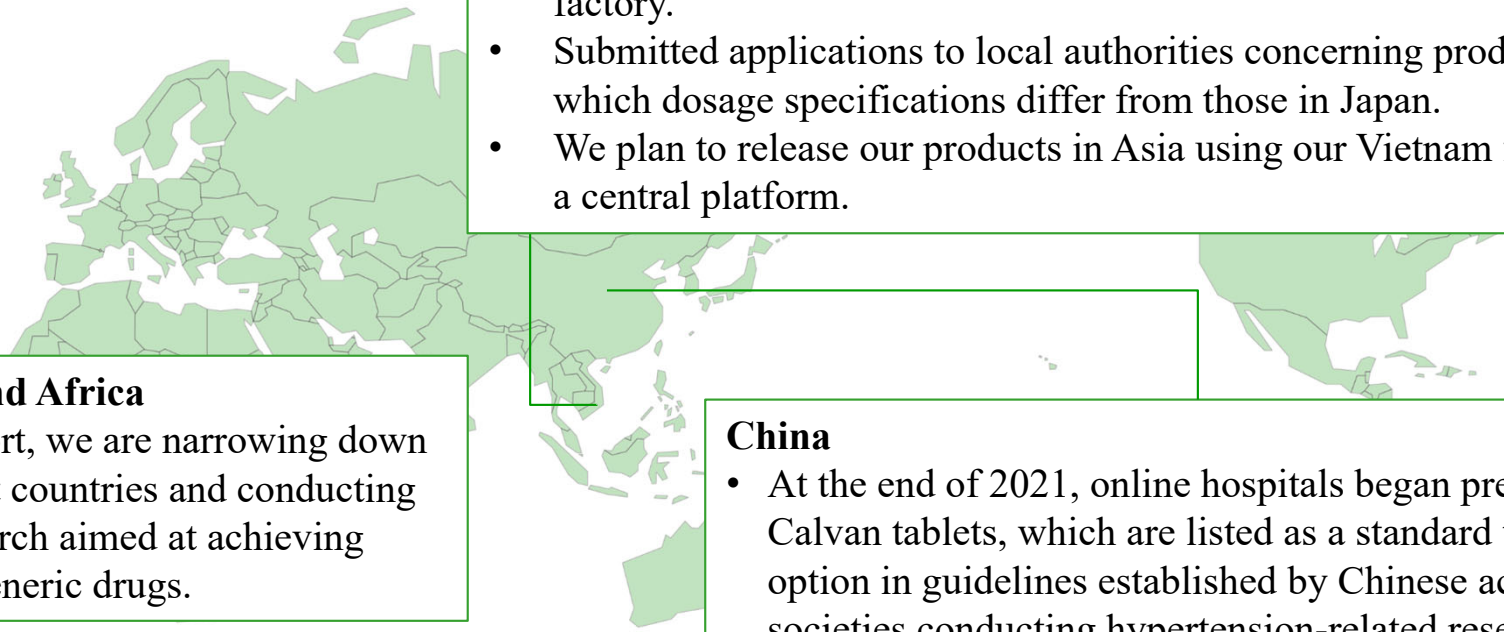
Source :Annual Health, Labour and Welfare Report 2018,

**Source : The Office of Pharmaceutical Industry Research, November 2021*

Oversea Business

We will realize results generated through business activities aimed at achieving our three goals in Japan overseas as well, particularly in other Asian nations.

Activities in Second Quarter FY2022



Vietnam

- Achieved smooth progress in terms of efforts aimed at moving product manufacturing from domestic factories to the Vietnam factory.
- Submitted applications to local authorities concerning products for which dosage specifications differ from those in Japan.
- We plan to release our products in Asia using our Vietnam factory as a central platform.

Middle East and Africa

With IFC support, we are narrowing down our list of target countries and conducting additional research aimed at achieving local sales of generic drugs.

IFC International Finance Corporation WORLD BANK GROUP

Creating Markets, Creating Opportunities

China

- At the end of 2021, online hospitals began prescribing Calvan tablets, which are listed as a standard treatment option in guidelines established by Chinese academic societies conducting hypertension-related research.
- Collaborated with a local company in the field of allergy testing and began providing technologies and materials.

Plan to Meet Listing Criteria of Prime Market

We opted for listing on the TSE's Prime Market. We plan to achieve full compliance in FY2026 by achieve progress through our management strategy with enhancing IR activities and an increased number of tradable shares..

State of Compliance with Listing Criteria

Criteria	Status	Targets	Need effort
Number of shareholders	3,711	800 or more	
Tradable shares	18,609 units	20,000 or more	レ
Total market capitalization of tradable shares	3.5 billion yen	10 billion yen or more	レ
% of tradable shares	44%	35% or more	
Average daily trading value	10 million yen	20 million yen or more	レ

Efforts Targeting Compliance

1. Steady execution of management strategies.
2. Improved Communication with Shareholders through enhanced IR activities.
3. Initiatives targeting an increase in tradable shares.

Our Target and Activities in FY2022

Contents	Target	Activities
Management index		
Profit target	1.3 billion yen in FY2026	0.5 billion yen in FY2022 forecast, 42.3% of progless rate in the first half.
Target price-to-earning ratio	x20 in FY2022—FY2026	Activities which leads to increase PER are ongoing such as: ・Promote DropScreen which additional measuring kit production line began operating. ・Development of DFP-14323 and DFP-17729
Number of tradable shares	20,000 unit or more in FY2022—FY2026	Optimized some cross-shareholdings.
Enhancement of IR activities		
Reflesh our Japanese website for investor, participate event for individual investor.		

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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.

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