Nippon Chemiphar Co., Ltd.

(TSE 4539)

Highlights of FY2021 Business Results

(Year ended March 31, 2022)

Chemiphar

Contents

Chemiphar

I. Summary of Results

Sales, Income

(¥mn)

	FY2020		FY2021		YOY*		FY2021 (Forecast)	
	Amount	% of Sales	Amount	% of Sales	Amount	Change (%)	Amount	Achieved (%)
Net Sales	**31,541**	**100.0**	**32,506**	**100.0**	**—**	**—**	**32,000**	**101.6**
Pharmaceutical products	30,423	96.5	31,501	96.9	—	—		
Others	1,117	3.5	1,004	3.1	—	—		
Cost of sales	**20,097**	**63.7**	**23,432**	**72.1**	—	—		
				8.4p		—		
SG&A expenses	**10,879**	**34.5**	**8,248**	**25.4**	—	—		
				(9.1p)		—		
Operating profit	**564**	**1.8**	**825**	**2.5**	**—**	**—**	**600**	**137.6**
Profit before income taxes and minority interests	**713**	**2.3**	**976**	**3.0**	**—**	**—**	**—**	**—**
Profit attributable to owners of the parent	**495**	**1.6**	**700**	**2.2**	**—**	**—**	**400**	**175.2**

*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.

(Reference)

Year-on-Year Comparisons Utilizing Previous Accounting Standards

(¥mn)

	FY2020	FY2021	Change
Net Sales	**31,541**	**36,081**	4,539
Pharmaceuticals	30,423	34,834	4,410
Others	1,117	1,246	128

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Pharmaceutical Sales

(¥mn)

	FY2020		FY2021			FY2021 Forecast	
	Amount	% of Sales	Amount	% of Sales	YOY* (%)	Amount	Achieved (%)
Total (① + ②)	27,322	100.0	28,037	100.0	—	27,400	102.3
① Generics	25,532	93.4	26,283	93.7	—	25,550	102.9
To medical institutions	24,531		25,043		—	24,370	102.8
To other makers	1,000		1,239		—	1,180	105.1
② Proprietary products and new drugs	1,790	6.6	1,754	6.3	—	1,850	94.8
Uralyt	730		623		—	580	107.4
Others	1,059		1,131		—	1,270	89.1
Total (① + ③)	26,696	—	27,139	—	—	26,400	102.8
③ Generics (ODM)	1,164	—	856	—	—	850	100.8

*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.

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Balance Sheet

(¥mn)

	FY2020	FY2021	Change	Components	
				Cash, deposits	1,060
				Notes, accounts receivable-trade	622
Current assets	30,446	33,495	3,048	Inventories	1,312
				Buildings and structures	(168)
Non-current assets	16,676	15,957	(718)	Land	(485)
Total assets	**47,124**	**49,453**	**2,329**		
				Purchase Obligations	2,039
				Short-term loans payable	177
Current liabilities	14,102	16,750	2,647	Accrued expenses	(106)
Non-current liabilities	15,006	14,202	(804)	Long-term loans payable	(715)
Net assets	18,014	18,501	486		
Liabilities, net assets	47,124	49,453	2,329		

	FY2020	FY2021	Change
Current ratio (x)	2.16	2.00	(0.16)
Equity ratio (%)	38.2	37.4	(0.8)

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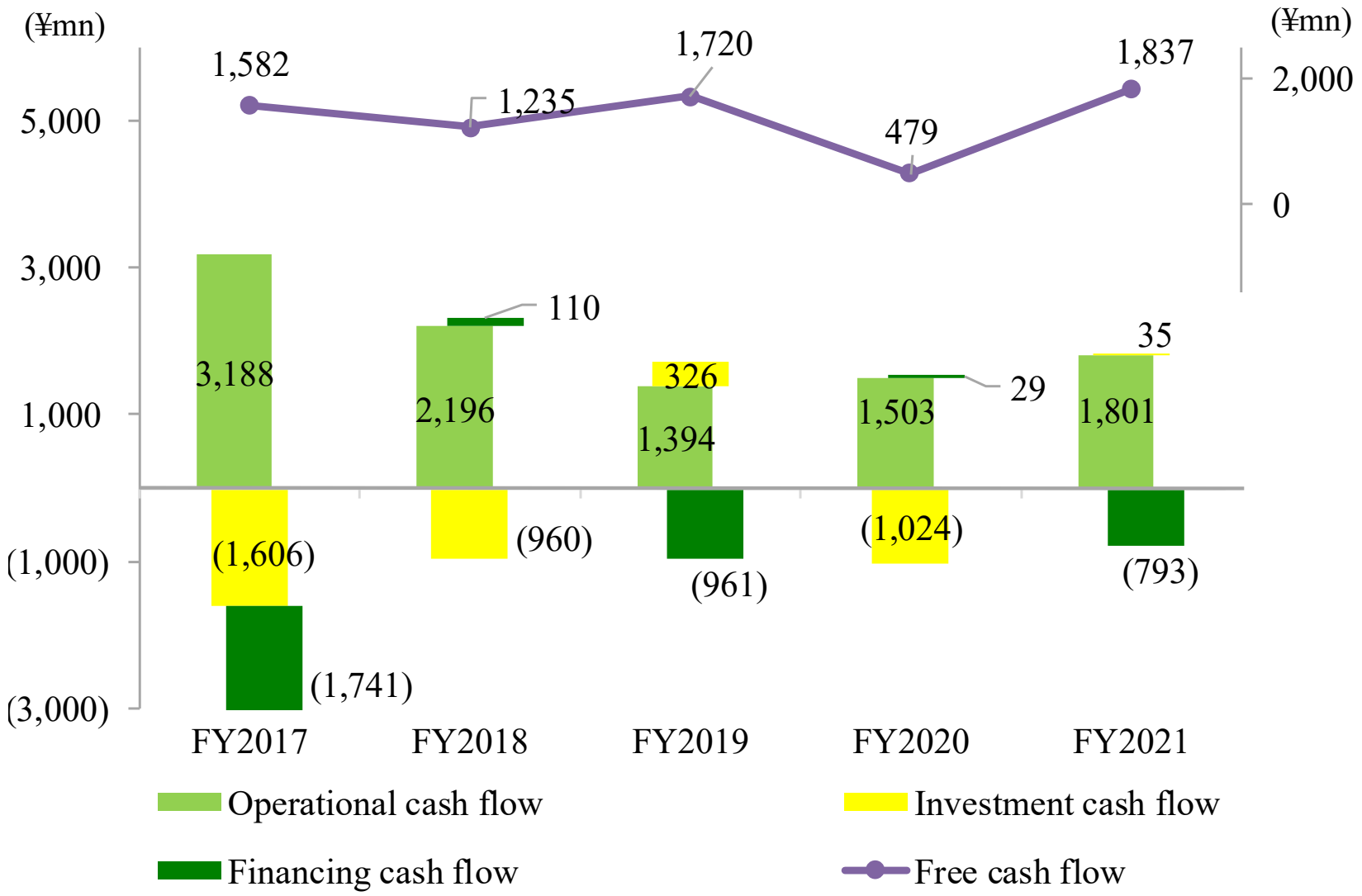
Cash Flow



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II. FY2022　Forecasts

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Sales and Income

(¥mn)

	FY2021		FY2022 (Forecast)		
	Amount	% of Sales	Amount	% of Sales	YOY (%)
Net Sales	32,506	100.0	35,000	100.0	7.7
Pharmaceuticals	31,501	96.9	—	—	—
Generics, proprietary products and new drugs	28,037	86.3	29,000	82.9	3.4
Diagnostics	2,163	6.7	3,120	8.9	44.2
Others	1,004	3.1	—	—	—
Operating profit	825	2.5	300	0.9	(63.7)
Profit before income taxes and minority interests	976	3.0	—	—	
Profit attributable to owners of the parent	700	2.2	550	1.6	(21.5)

Main factors driving changes in net sales

(–) NHI drug price reduction in April 2022
(–) Tendency for patients to refrain from medical examinations in the midst of the COVID-19 pandemic.
(+) Continuous demand stemming from quality issues at other generic companies
(+) Enhancing DropScreen™
(+) Launching new generics

Main factors affecting profit

(–) Decline in gross profit caused by NHI drug price reduction
(–) Increase in R&D costs due to progress in new drug development
(+) Soaring materials and logistics costs

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Pharmaceutical Sales and Expenditures

Pharmaceutical Sales

(¥mn)

	FY2021		FY2022 (Forecast)		
	Amount	% of Sales	Amount	% of Sales	YOY (%)
Total	28,037	100.0	29,000	100.0	3.4
Generics	26,283	93.7	27,440	94.6	4.4
To medical institutions	25,043		26,600		6.2
To other makers*	1,239		840		(32.2)
Proprietary products and new drugs	1,754	6.3	1,560	5.4	(11.1)
Uralyt	623		580		(6.9)
Others	1,131		980		(13.4)
Total	27,139	—	28,450	—	4.8
Generics (ODM)	856	—	1,010	—	17.9

* Includes exports

Expenditures

(¥mn)

	FY2021	FY2022 (Forecast)	YOY (%)
R&D expenses	2,392	3,000	25.4
Capital expenditure	1,131	1,150	1.7
Depreciation and amortization	1,586	1,600	0.8

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III. Management Strategy

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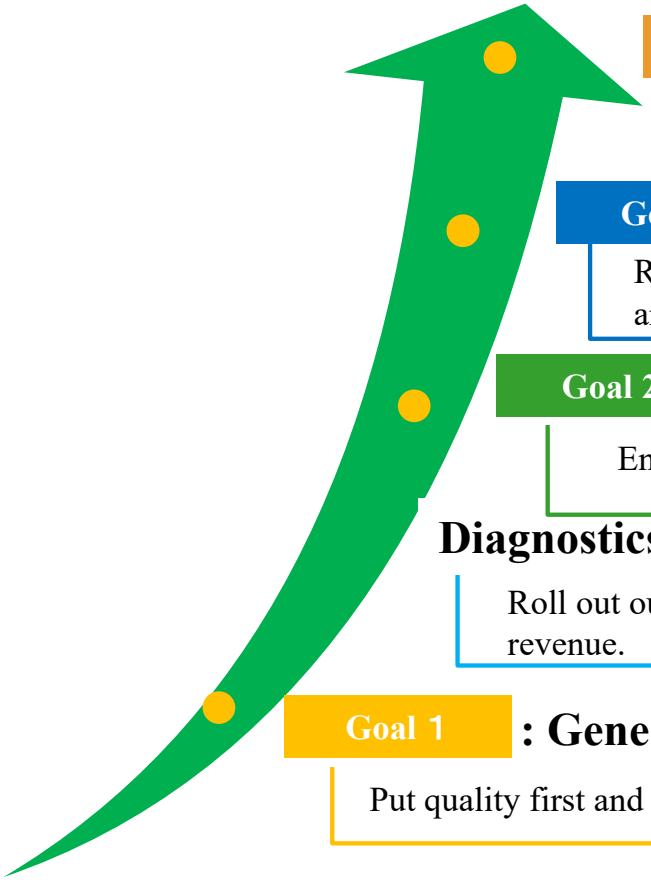
Three Plus 1 Principal Goals

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.

Business strategy by Three Plus 1 Principal Goals



Plus 1 : Overseas Business

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

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Goal 3 : Drug discovery

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

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Goal 2 : Alkalizers

Ensure multifaceted application of our expertise regarding alkalization therapy

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Diagnostics

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

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Goal 1 : Generics

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

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Management Strategy 1

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

Goal	Activity	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Generics	Launch value-added generics and introduce products from other company	Aim to launch two or more value- added products per year.									
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 other health-related products.				
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-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. Contribute to profits by out-licensing NC-2700 promptly.						

Management Strategy 2

Goal	Activity	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Drug discovery	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 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	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 Drugs

We are responding to market needs by establishing a framework for higher production enhancing our quality assurance. Responding to drastic changes in our business environment, we strengthen profitability through developing high value-added products, reducing costs, and improving sales efficiency.

Quality Assurance

- **We fulfill our fundamental responsibility as a pharmaceutical maker by maintaining our ceaseless efforts targeting a stronger quality assurance system.**
- In support of quality assurance, 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.
- Strengthening of groupwide quality assurance
  - ✓ **April 2022: Established the Group Quality Assurance Management Department**
  - ✓ **Formulated the Group Quality Policy and strengthened our groupwide quality management system**

Development

- We shift the focus of our product development to value-added drug formulations that meet clinical needs.
- Meanwhile, we will maintain competitiveness through patent strategies and the discovery of niche products.

Manufacture

- Expanding production at the Vietnam factory
- Cutting manufacturing costs through the addition of high-quality and affordable APIs from overseas while securing stable means of supply.

- We strengthen our manufacturing system in response to market needs by introducing new machines and recruiting additional staff.

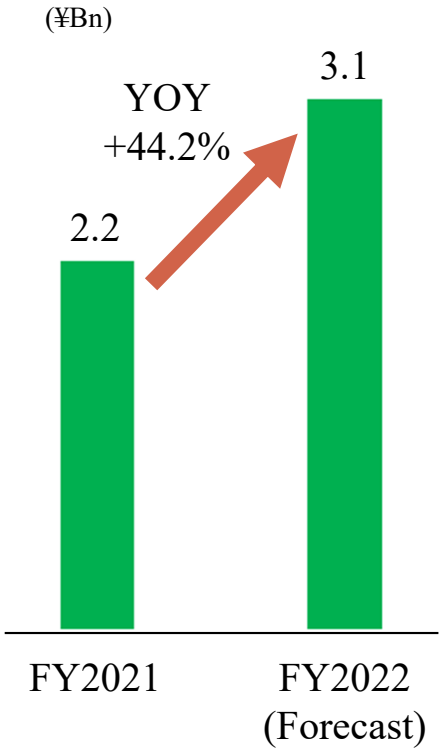
Sale

- The Group Pharmaceutical Sales Headquarters centrally supervises pharmaceutical sales divisions within both the Company and its subsidiary Nihon pharmaceutical industry supports a diverse range of sales channels.
- In pursuit of a faster PDCA cycle, we apply AI technology to our customer management and strategy planning while adopting a new sales force automation system.

Diagnostics

To maximize revenue, we strengthen our diagnostics business by rolling out DropScreen™ in Japan and abroad and marketing both DP3000 and IgE NC in China.

FY2022 Sales Forecast



Activities for main Products

DropScreen™

Domestic Market

- To facilitate the creation of a new market for in-house allergy testing (which mainly outsource traditionally), we promote its advantages, which include efficiency in terms of space and the ability to screen for 41 allergens in just 30 minutes using only a single drop of blood.
- We promote joint sales activities with FUJIFILM Wako Pure Chemical Corporation on a full scale as we aim to install 1,000 units in Japan as quickly as possible.

Overseas Market

- We will implement initiatives targeting expansion in both Europe and Southeast Asia.

DP3000

China

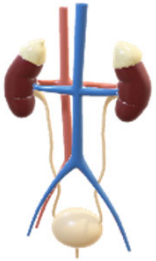
- We provide technologies to local companies in China attempting to achieve domestic production of DP3000.
- We have secured approval for the use of reagent IgE NC when testing for 20 different allergens and have begun selling the reagent for this purpose commercially.
- Moving forward, we will further strengthen our lineup of reagents in China.

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 ）



Preventing progress of chronic kidney disease

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

Uralyt
- Gout
- Hyperuricemia
- Acidosis

Health foods
（reduce feelings of fatigue）

Expand Alkalizers to Cancer and CKD

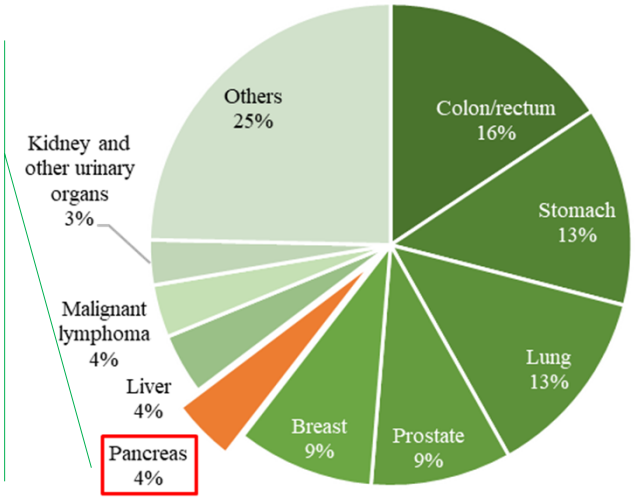
As the sole pharmaceutical company focused on alkalizers, we view DFP-17729, which has high potential for application as a valuable cancer and CKD suppressant agent, as a secondary growth driver capable of complementing our generic drugs and diagnostics.

DFP-17729

- Concluded a license agreement with Delta-Fly Pharma, Inc.
- Finished case registration for a phase 2a trial in November 2021.
- Non-clinical study indicated anticancer effects when administered in combination with standard anticancer agents.

Projected Number of Cancer Incidence by Site (2020)

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.

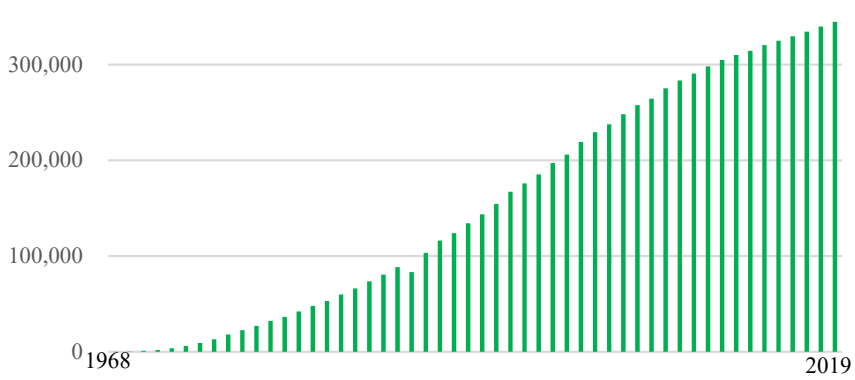


Source :CANCER STATISTICS IN JAPAN ─ 2021, Foundation for Promotion of Cancer Research

Inhibit the progression of CKD

- The potential number of CKD patients is estimated to be 13 million.
- Sufferers of CKD ultimately require dialysis once their conditions worsen. Increases in the number of patients requiring dialysis are causing a variety of societal 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 possibilities targeting CKD by utilizing AI and clinical data.

Trends in the prevalent dialysis patient count



Source :Annual dialysis data report 2019, the Japanese Society for Dialysis Therapy

Pipeline

Item	Function (Target)	Pre-clinical / Phase 1 / Phase 2 / Phase 3	Notes
NC-2400	PPAR-δ agonist (Lipid metabolism abnormalities)	Phase 1	・Finished Phase 1. ・Licensed to Abionyx Pharma SA (France).
NC-2500	XOR inhibitor (Hyperuricemia, gout)	Pre-clinical / Phase 1	・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)	Pre-clinical / Phase 1	・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)	Pre-clinical	・Finished preclinical trial and are conducting licensing-out activities.
NC-2800	δ opioid receptor agonist (Depression/Anxiety)	Pre-clinical / Phase 1	・Selected by AMED for its funding program on January 2018 and began phase 1. ・Concluded a collaborative research and development agreement and an option agreement with Sumitomo Pharma Co., Ltd.
DFP-17729	Cancer microenvironment improving agent (Pancreatic cancer)	Pre-clinical / Phase 1 / Phase 2	・Developed by Delta-Fly Pharma, Inc. ・Moved to a phase 2a trial and finished case registration in November 2021.
DFP-14323	**Anti cancer agent (non-small cell lung cancer)**	Pre-clinical / Phase 1 / Phase 2 / Phase 3	**・Concluded a license agreement with DFP and acquire exclusive rights to market in Japan.** **・Showed positive results in phase 2.**
Calvan	A1β1 blocker (Huntington's disease)	Phase 2	・Licensed to SOM Biotech SL (Spain). ・Completed the phase 2a trial and presented the data at a conference held in October 2021.

As of March 2022.

In-house drug development

Development with other companies

Other companies or physician-initiated development

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DFP-14323 (Anti Cancer Agent)

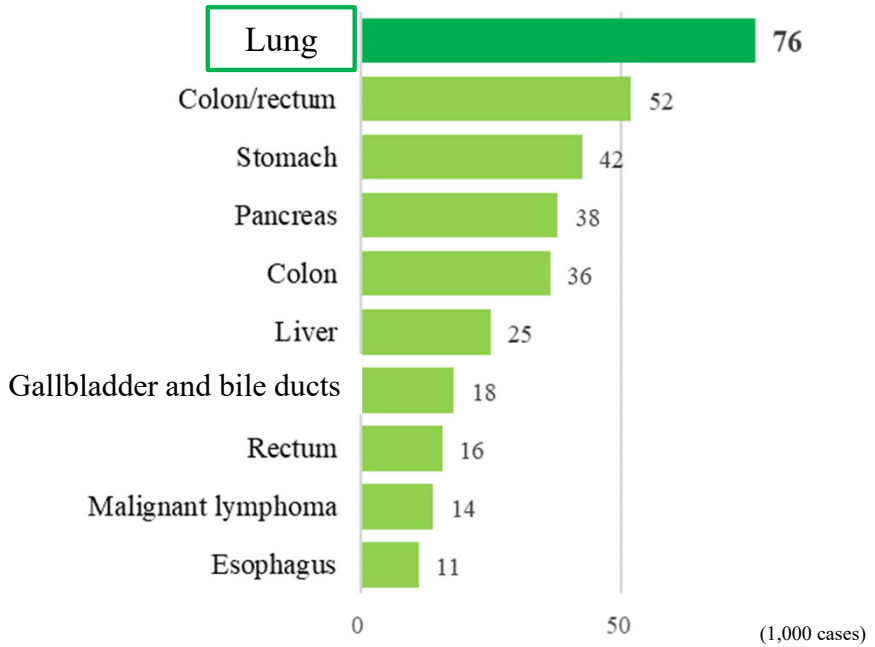
DFP-14323 targets lung cancer, which causes more deaths than any cancer affecting other parts of the body. We will aim to generate synergy through our sales activities by handling other oncological drugs in addition to DFP-17729.

Outline

Month of Conclusion	March 2022
Developer	Delta-Fly Pharma, Inc.
Details	Chemiphar will market this drug in Japan once approval has been granted.
Nonproprietary Name	Ubenimex
Mechanism	Binds to aminopeptidase N (a surface marker for cancer stem cells also known as CD13) that appears on the surface of immune-related cells to enhance immune response in cancer patients.
Target	Non-small cell lung cancer (NSCLC) Stage III and IV with epidermal growth factor receptor (EGFR) mutation positive.
Character	Improves the effectiveness of standard anticancer agents without increasing side effects.
Estimated Schedule	Finished Phase 2, plan to application for approval in the middle of 2020s.

Cancer sites with the highest mortality rate

(Males and females, as of 2020, in Japan)



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

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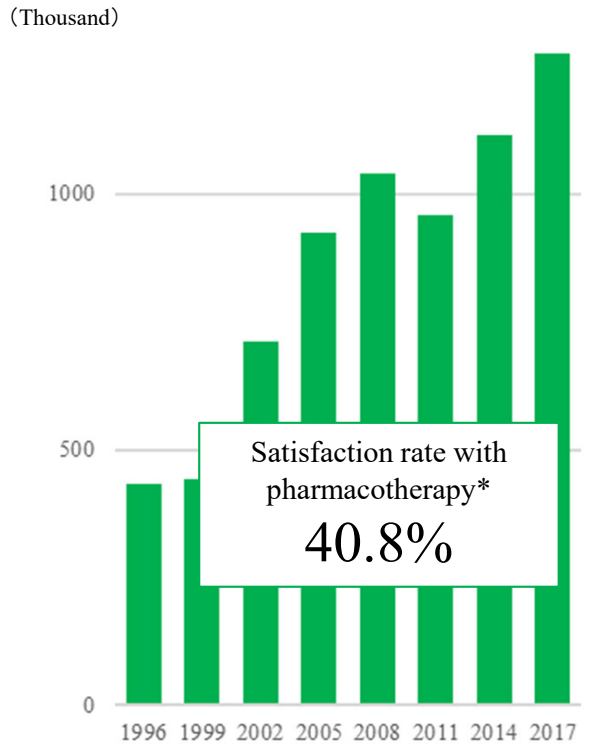
NC-2800 (Delta Opioid Receptor Agonist)

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

Month of Conclusion	June 2021
Details	Concluded a collaborative research and development agreement and an additional option agreement 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.
Status	Phase 1 (Begun July 2021)
Function	Delta opioid receptor agonist
Target	For depression, anxiety
Character	Less of the side-effects that these drugs have been known to cause and high levels of safety and efficacy.
Estimated Schedule	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.

Number of mood disorders



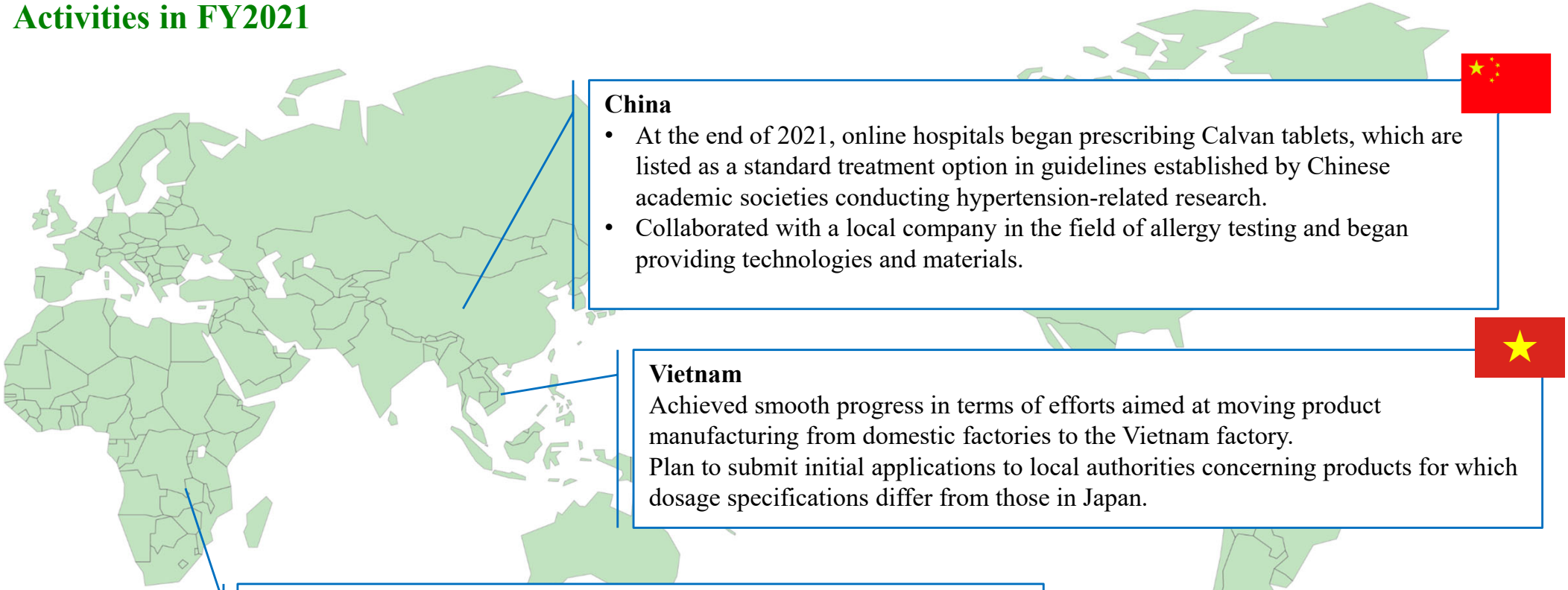
Source :Annual Health, Labour and Welfare Report 2018,

**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 FY2021



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.

Vietnam

Achieved smooth progress in terms of efforts aimed at moving product manufacturing from domestic factories to the Vietnam factory.
Plan to submit initial applications to local authorities concerning products for which dosage specifications differ from those in Japan.

Middle East and Africa

Through collaboration with the International Finance Corporation (IFC), launched research targeting local sales of generic drugs in the Middle East and Africa.

IFC International Finance Corporation WORLD BANK GROUP

Creating Markets, Creating Opportunities

For further information contact:
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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.