



TSUMURA & CO.

Business Results for Fiscal 2023

May 10, 2024

Event Summary

[Company Name]	TSUMURA & CO.	
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[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	10	
	Terukazu Kato	President, Representative Director, CEO
	Kei Sugii	Director, Co-COO
	Muneki Handa	Director, CFO
	Tadashi Okada	Director (Outside Director)
	Susumu Adachi	CHRO in charge of Human Resources Department
	Yukinori Sorada	Executive Officer, Head of Sales and Marketing Division
	Akihito Konda	Executive Officer, Head of Research & Development Division
	Shoichi Kumagai	Executive Officer, Head of , Production Division
	Atsushi Kaneko	Head of International Pharmaceutical Research & Development Division

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Presentation

Kitamura: It's time to begin the briefing for the business results for FY2023 of TSUMURA & CO. Thank you very much for taking time out of your busy schedule to join us today.

We are holding this year's briefing in a hybrid format, with both a head office venue and a webcast. The explanation will be provided in line with the presentation materials posted on our website, so please have them ready at hand or refer to the materials that will be projected.

I would now like to introduce today's attendees. Kato, President, Representative Director, CEO. Sugii, Director, Co-COO. Handa, Director, CFO. Okada, Outside Director. CHRO, Adachi. Sorada, Executive Officer, Head of Sales and Marketing Division. Konda, Executive Officer, Head of Research & Development Division. Kumagai, Executive Officer, Head of Production Division. Kaneko, Head of International Pharmaceutical Research & Development Division. These are the nine members present. I am Kitamura from the Corporate Communications Department, and I will be your moderator. Thank you very much for your cooperation.

Agenda



- 01 Moving Towards Realizing the Long-Term Management Vision—TSUMURA VISION “Cho-WA” 2031
- 02 Business Results for Fiscal 2023 and Earnings Forecast for Fiscal 2024
- 03 Progress in US development (TU-100)

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This is today's agenda. We will explain the three themes you see. The briefing will take approximately 50 minutes. After all explanations, we would like to answer any questions you may have. The program is scheduled to end at 2:30 PM.

Now, Mr. Kato will explain our efforts to realize the Long-Term Management Vision 2031. Please begin.

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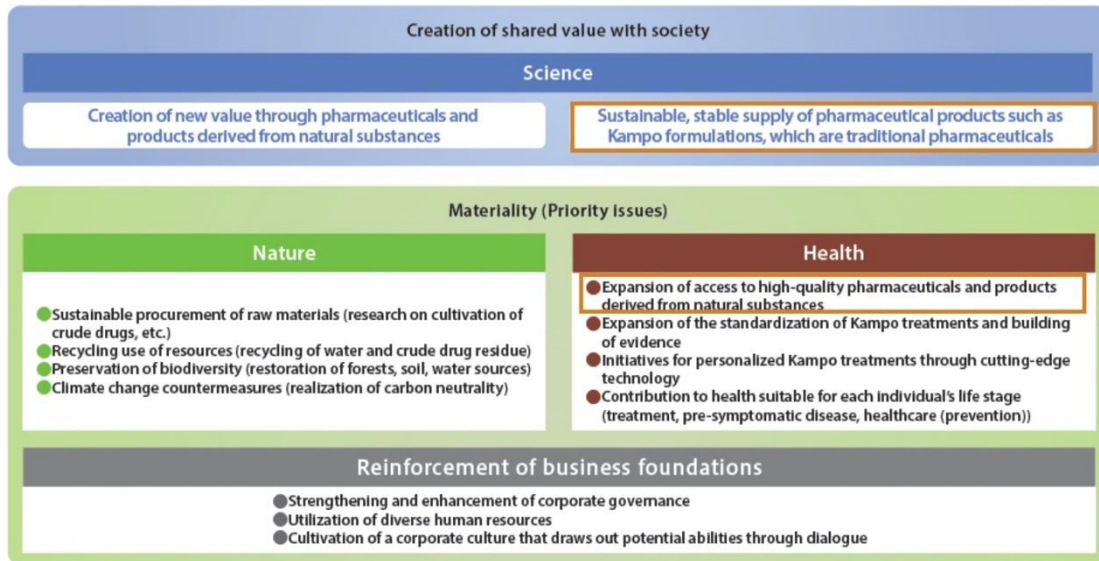


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Aiming to Establish a Global Standard for Pharmaceuticals Derived from Natural Ingredients



【Corporate Purpose】 “Lively Living for Everyone” 【Corporate Value】 “Best of Nature and Science”



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Kato: My name is Kato. We would like to express our sincere appreciation and gratitude to all of you for your continued support of our company and Kampo. Thank you again for taking time out of your busy schedule to join us.

Yesterday, we announced our financial results for FY2023. We are grateful for the significant turnaround in the business environment surrounding Kampo Pharmaceuticals, and we are working diligently to allocate resources to further strengthen the stable supply system for Kampo products.

In response to this change in the business environment, we are determined to solidify our presence as a manufacturer of global-quality pharmaceuticals derived from natural ingredients, and further work to expand demand for Kampo treatments in new areas and diseases in the urgent social issues facing our country.

Based on the Group's Corporate Purpose "Lively Living for Everyone" and the Corporate Value "The Best of Nature and Science," we aim to realize a better society that is rich in spirit and vitality through the creation of shared values with society as shown.

The Pharmaceutical Industry Vision 2021, which outlines the direction of Japan's pharmaceutical industry policy, aims to realize two goals: to contribute to the extension of healthy life expectancy and industrial economic development in Japan; and to pass on to future generations a society in which citizens can receive quality medical care with peace of mind through the quality assurance and stable supply of pharmaceutical products.

In line with this policy direction, the Group will contribute to the extension of healthy life expectancy in Japan by expanding access to high-quality drugs and pharmaceuticals derived from natural ingredients through a sustainable and stable supply of traditional Kampo products and other pharmaceutical products.

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Realization of a Global Quality for Pharmaceuticals Derived from Natural Ingredients



Pharmaceutical requirements: Possesses therapeutic benefits (efficacy) but no side effects (safety)



Degree to which requirements are fulfilled: Confirmed in studies (clinical trials)



Investigational new drug (IND): Gold standard quality



The efficacy and safety of pharmaceutical products is guaranteed through the constant supply to the front lines of medicine of pharmaceutical products that are equivalent to INDs evaluated in clinical trials.



Good quality pharmaceutical products are those products for which the efficacy and safety is guaranteed to be constantly equivalent to those that have been clinically confirmed
⇒ **Pharmaceutical products that have been standardized to guarantee their medical reproducibility**

Dr. Yukihiro Goda, Honorary Director, National Institute of Health Sciences (NIHS) 5

In order to ensure the quality and stable supply of pharmaceuticals as required by the pharmaceutical industry policy, we continue to conduct quality design and basic clinical research on Kampo products in order to establish a global standard for pharmaceuticals derived from natural ingredients, and establish a traceability system by integrating all processes from the cultivation and procurement of raw material crude drugs to their manufacture and sale by our own group companies.

As you can see, Dr. Yukihiro Goda, Honorary Director of the National Institute of Health Sciences, defines a good drug as one that is standardized to ensure reproducibility in medicine. The quality of Kampo products, which are pharmaceuticals derived from natural ingredients, varies due to the fact that they are natural products. The key to standardization of pharmaceutical Kampo preparations is homogeneity, which minimizes the variation of raw material crude drugs. This is where our group's technology and know-how are concentrated.

Furthermore, in the US development process, the level of quality control has been significantly improved due to the wide range of stringent requirements.

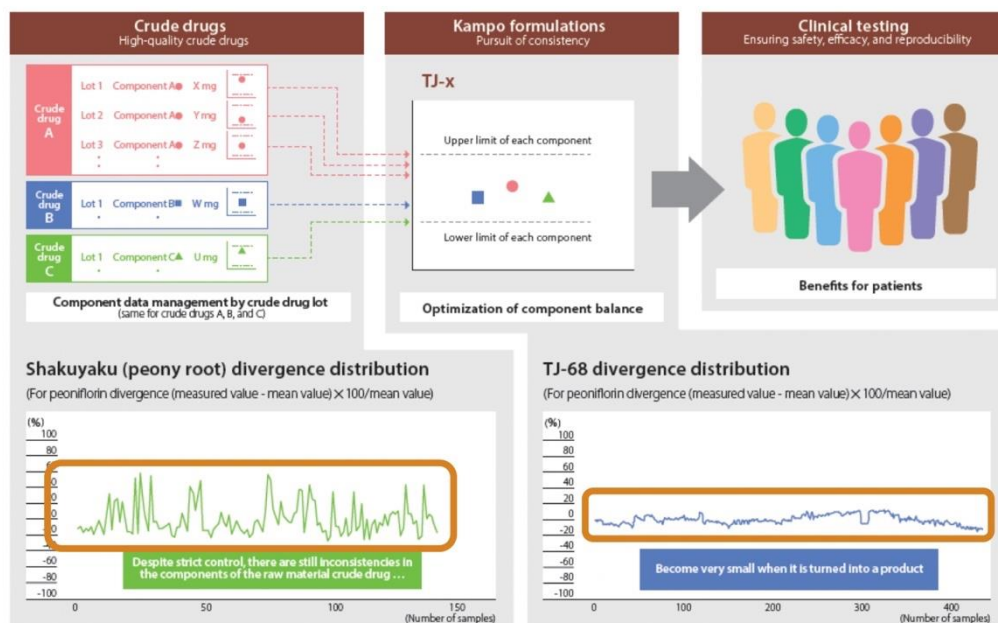
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Standardization to guarantee medical reproducibility [High level of difficulty]



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We are aware that our market share of over 80% in the medical Kampo market for many years is due to the fact that expert physicians have realized the reproducibility of medical treatment with our Kampo products, and we are committed to further clarifying the mechanism of action of Kampo products, building evidence, and maintaining and improving quality.

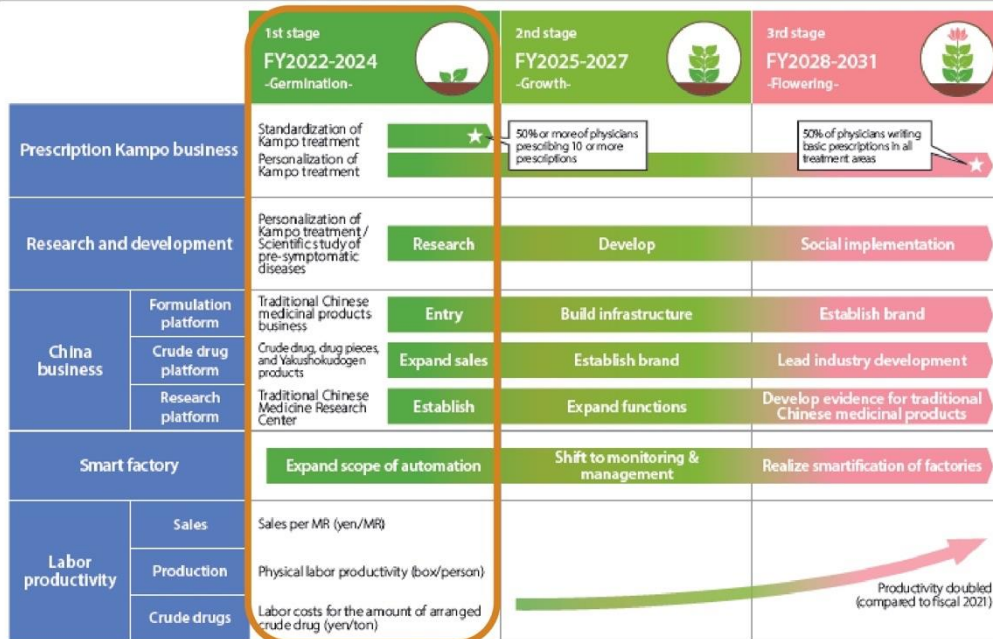
As an example, the deviation distribution of paeoniflorin, the main component of peony, a raw material crude drug, is kept within a certain range by continuous procurement of crude drugs from a certain region through contract cultivation. On the other hand, the paeoniflorin deviation distribution of TJ-68, the Kampo product shown at the bottom right, is tightly controlled within plus or minus 20%.

Although the national standard is plus or minus 50%, our group, based on the belief that the quality of Kampo products starts in the field, aims to achieve standardization at the global standard level to guarantee reproducibility in medicine, which is highly challenging for pharmaceuticals derived from natural ingredients.

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With this Corporate Purpose, we practice management aimed at long-term corporate value creation by embodying our Corporate Value and formulating a long-term management vision of what we should be aiming for 10 years from now, which we have backcasted.

In order to realize our Vision 2031, 10 years from now, we have established a medium-term management plan as a milestone, setting numerical targets and strategic challenges as achievement goals. Currently, we are working to achieve the goals of our first medium-term management plan.

We are also determined to fulfill our responsibilities as a prime market-listed company that contributes to the development of Japan's industrial economy and the formation of an attractive stock market. In order to become an investment target for many investors in terms of liquidity, governance, operating results, and financial condition, which are the criteria for prime market listing, we will practice management with an awareness of cost of capital and capital efficiency.

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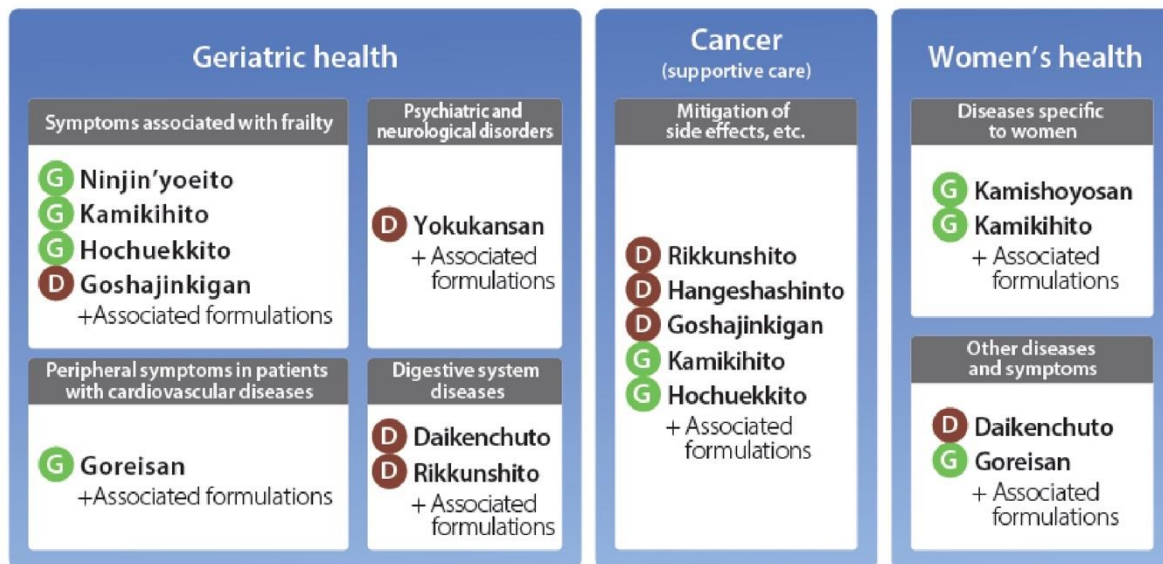
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Three Important Medical Domains that are Urgent Issues in Japan



D Drug-fostering program formulations **G** "Growing" formulations



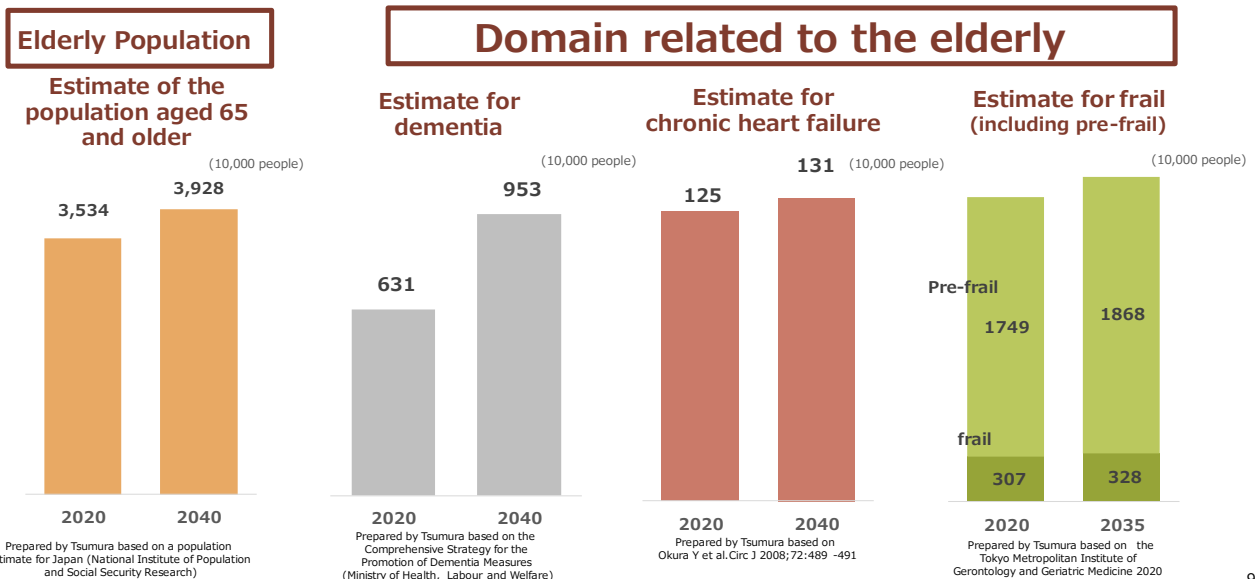
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In the three priority medical fields of the elderly, oncology (supportive care), and women's health, which are pressing social issues in Japan, we are focusing on the expansion of evidence-based standard Kampo treatment and on initiatives for personalized Kampo treatment.

Increasing trend of diseases in related fields with the increase in the elderly population



Estimated that the number of patients with dementia, chronic heart failure and frail is trending upward in tandem with the increase in the number of elderly



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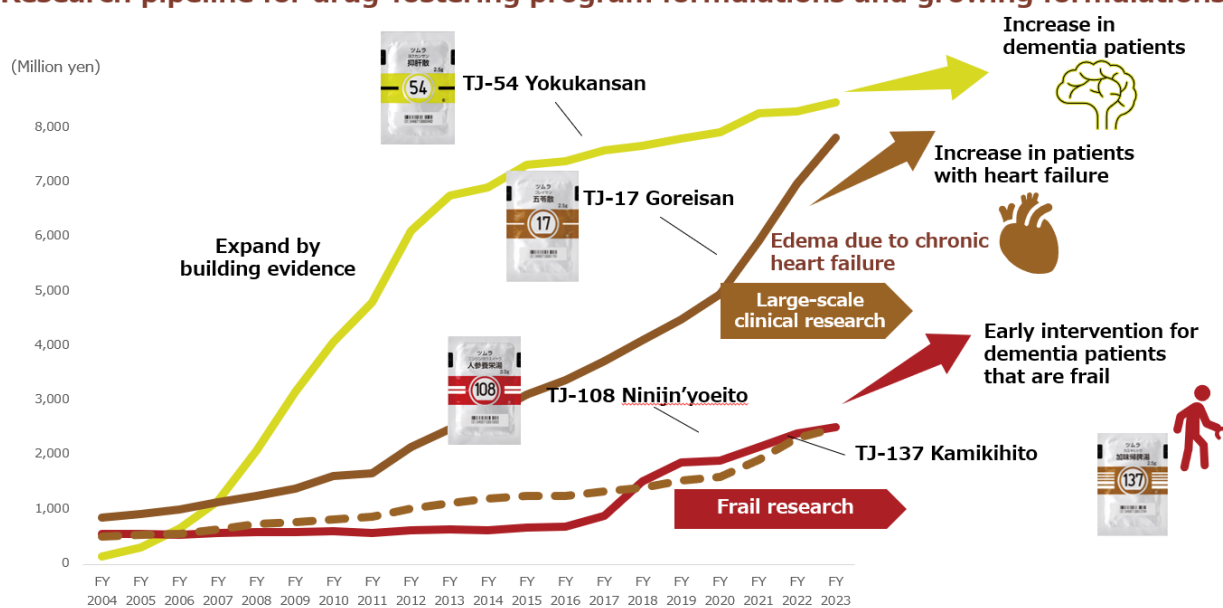
We are also conducting basic clinical research to contribute to improving the frailty of the elderly and their general condition for cancer supportive care, based on the recommendations of the Study Group on the Future Vision for Kampo—Responsibility for People’s Health and Healthcare, which was established in 2016.

Japan Kampo Medicines Manufacturers Association, an industry organization of Kampo, of which I am the chairman, has also formulated The Future Vision for Kampo Medicines 2040, and is conducting activities based on milestones and action plans in anticipation of the year 2040, when the population over 65 years old will peak.

As you can see, with the increase in the elderly population, the number of patients with dementia, chronic heart failure, brain diseases, and patients with frail conditions is expected to increase. We will play a role in these issues, which is possible only with multi-component Kampo products, and help extend healthy life expectancy.

Domain related to the Elderly, Contributing to the Extension of a Healthy Life Expectancy

Research pipeline for drug-fostering program formulations and growing formulations



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Under Japan's medical insurance system, which boasts universal coverage and free access, we will accelerate basic clinical research focusing on "drug fostering" program formulations and "growing" formulations to respond to unmet medical needs, such as dementia, heart failure, and other diseases and early responses to frail conditions, in order to contribute to extending healthy life expectancy.

Based on Kampo medicine, the Company aims to expand access to Kampo treatment with an increase in the number of physicians prescribing Kampo products, and to expand evidence-based Kampo treatment in areas and diseases that are difficult to treat through research pipeline-like exploration as an R&D-driven Kampo product manufacturer.

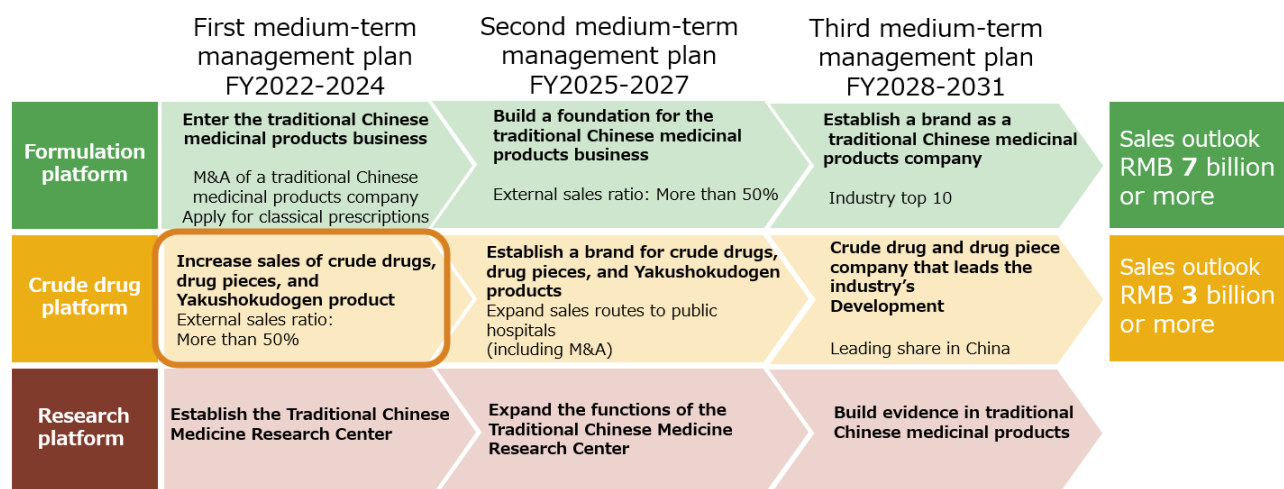
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Vision for the China business: Contributing to the health of the citizens of China



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The materiality of the Group, as indicated at the beginning of this document, is the same for our China business. Traditional Chinese medicines and traditional Chinese medicinal products are also traditional pharmaceuticals derived from natural ingredients, and medical issues in an aging society will need to be addressed in China as they are in Japan. With reference to the results of treatment in Japan, we will also contribute to the health of the Chinese people, who are the main source country of raw material crude drugs.

We are developing our business in line with the milestones for each of the China business platforms you see, but our top priority for the current fiscal year is to enter the China business in the formulation platform, where we have yet to see results due to the political situation between Japan and China.

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China Business/Crude Drug PF: Products/Services Owing to High-Quality Crude Drugs TSUMURA



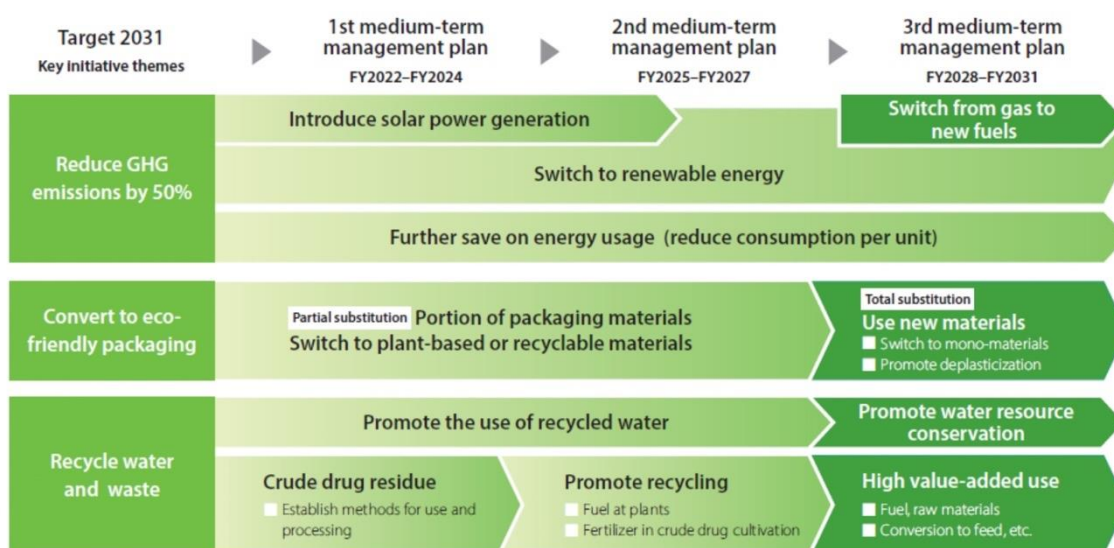
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In our China business and crude drug platform, we have been aggressively expanding sales channels for crude drugs in order to gain recognition for the quality of Ping An Tsumura Medicine's crude drugs and achieved sales of JPY18.7 billion in FY2023.

From FY2024, we will work to develop end-users by selecting customers with an emphasis on improving profitability, selling drug pieces and providing value-added services, as well as developing new products based on the concept of Yakushoku Dogen.

Sustainability Targets 2031 TSUMURA

Sustainability Vision : Living with nature for tomorrow.



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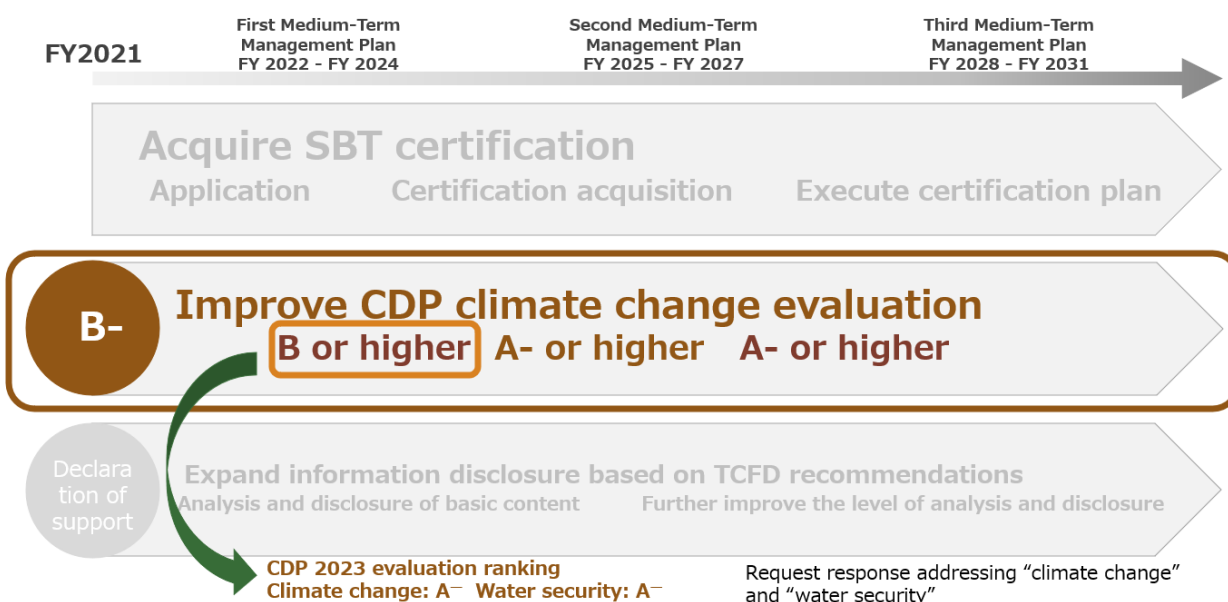
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Finally, regarding our sustainability initiatives, we are working on each of the items listed in our Sustainability Targets 2031 under our Sustainability Vision "Living with nature for tomorrow."

Improve Evaluations by Environment-related Rating Agencies



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We will report on our progress at the end of the first medium-term management plan, and I am pleased to report on the results of our evaluation released on February 6, 2024 by CDP, Carbon Disclosure Project, an international rating agency for environmental matters.

For our company, climate change and water security are the CDP assessment targets. For climate change, we received a B- in 2021, a B in 2022, and an A- in 2023. For water security, the Company was rated B in 2021, A- in 2022, and A- in 2023 again. As you can see, we were able to achieve the CDP evaluation 1 year ahead of schedule.

We will continue to work toward maintaining and improving our reputation and achieving our Sustainability Targets 2031.

This concludes my explanation. Thank you very much.

Kitamura: Thank you very much. Mr. Handa will now explain the financial results for FY2023 and the forecast for FY2024. Please begin.

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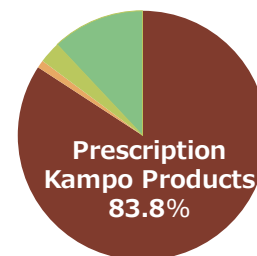


Business Results for FY 2023



【Million yen】	Revised forecast for FY 2023 (Revised on February 6)	FY2023 results	Vs.planned	YoY	
				Amount	Change
Sales	152,000	150,845	99.2%	+10,801	+7.7%
Domestic business	133,300	132,099	99.1%	+7,400	+5.9%
China business	18,700	18,745	100.2%	+3,400	+22.2%
Operating profit	19,500	20,017	102.7%	(899)	(4.3)%
Domestic business	20,100	20,531	102.1%	(658)	(3.1%)
China business	(600)	(514)	—	(240)	—
Ordinary profit	22,400	23,493	104.9%	+40	+0.2%
Profit attributable to owners of parent	16,200	16,707	103.1%	+225	+1.4%
PL translation rate (CNY)	19.00	19.83	—	+0.28	—

Ratio to total sales



- China business : Crude Drug Platform 12.4%
- Domestic business : OTC Kampo etc. 2.9%
- Domestic business : Other prescription pharmaceuticals 0.9%

*Forex rate at the time overseas subsidiaries' PLs were incorporated; differs from the import rate for raw material crude drugs

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Handa: My name is Handa. I will now explain our financial results for FY2023 and our forecast for FY2024.

First, here is a summary of the financial results for FY2023. Although sales fell slightly short of the revised plan, each of the profits achieved the revised plan. Sales totaled JPY150.8 billion, 99.2% of the revised plan and up 7.7% from the same period last year. The breakdown is as shown in the pie chart, with the domestic business accounting for JPY132 billion and the China business for JPY18.7 billion, and the sales composition ratio is as shown in the pie chart.

Operating profit was JPY20 billion, 102.7% of the revised plan and down 4.3% from the same period last year. Ordinary profit was JPY23.4 billion, 104.9% of the revised plan and up 0.2% from the same period last year. Profit attributable to owners of parent was JPY16.7 billion, 103.1% of the revised plan and up 1.4% from the same period last year.

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Key Points in Performance



Net sales and profits at each level nearly in line with revised plan

Net sales	150,845	million yen	Achievement rate	99.2%	YoY	+7.7%
<ul style="list-style-type: none"> ■ Domestic business Total sales of the 129 prescription Kampo products : 126,357 million yen, up 5.9% year-on-year Total sales of OTC Kampo formulations and other healthcare products : 4,439 million yen, up 11.9% year-on-year ■ China business Raw material crude drugs, drug pieces, Yakushokudogen products, etc. : 18,745million yen, up 22.2% year-on-year 						
Operating profit	20,017	million yen	Achievement rate	102.7%	YoY	(4.3)%
Operating profit margin	13.3	%	vs. Plan	+0.5pt	YoY	(1.6)pt
<p>Cost-to-sales ratio: 54.4%, down 0.5pt vs. plan and a rise of 3.2pt year-on-year Versus plan: Manufacturing input was small for powdered extracts at the Tianjin Plant Year-on-year: Impact mainly due to a rise in crude drug procurement expense, depreciation in the value of the yen against major currencies, and raw material expenses continuing to trend at a high level SG&A ratio: 32.4%, up 0.2pt vs. plan and down 1.4pt year-on-year Year-on-year: Sales growth absorbed growth investments, including the DX of R&D and the Kampo Value Chain</p>						
Ordinary profit	23,493	million yen	Achievement rate	104.9%	YoY	+0.2%
<ul style="list-style-type: none"> ■ Foreign exchange gain primarily related to loans to overseas subsidiaries: 2,193 million yen, up 684 million yen year-on-year <p>*Foreign exchange gains of 1,338 million yen were recorded at the time of the February 7 revised forecast revision.</p>						
Profit attributable to owners of parent	16,707	million yen	Achievement rate	103.1%	YoY	+1.4%
<p>Posted extraordinary loss (impairment loss and COVID-19 related loss) in the prior fiscal year</p>						

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I will explain the key points of the financial results.

Sales of 129 prescription Kampo products in the domestic business grew 5.9% YoY to JPY126.3 billion. OTC Kampo medicine, etc. grew 11.9% YoY to JPY4.4 billion due to an increase in the number of outlets handling these products.

Sales in the China business grew 22.2% YoY to JPY18.7 billion due to a significant increase in sales of raw material crude drugs.

The cost of sales ratio was 54.4%, down 0.5 points from the revised plan, due to lower than initially expected input of extract powder at the Tianjin plant, which has a high cost of sales ratio in the early stage of operation. Compared to the same period of the previous year, the increase was plus 3.2 points due to higher crude drug procurement costs, yen depreciation, and high prices of raw materials.

The SG&A-to-sales ratio was 32.4%, almost in line with the revised plan, up 0.2 points. Compared to the same period of the previous year, the increase in R&D expenses and growth investments for the DXing of the Kampo value chain, etc., was absorbed by the increase in sales, resulting in a negative 1.4 points. As a result, operating profit margin was 13.3%, up 0.5 points from the revised plan and down 1.6 points from the same period last year.

Ordinary profit increased 0.2% YoY due to the impact of a foreign exchange gain of JPY2.1 billion related to loans to overseas subsidiaries resulting from yen depreciation. Profit attributable to owners of parent increased 1.4% YoY due to the effect of the reversal of extraordinary losses recorded in the previous fiscal year.

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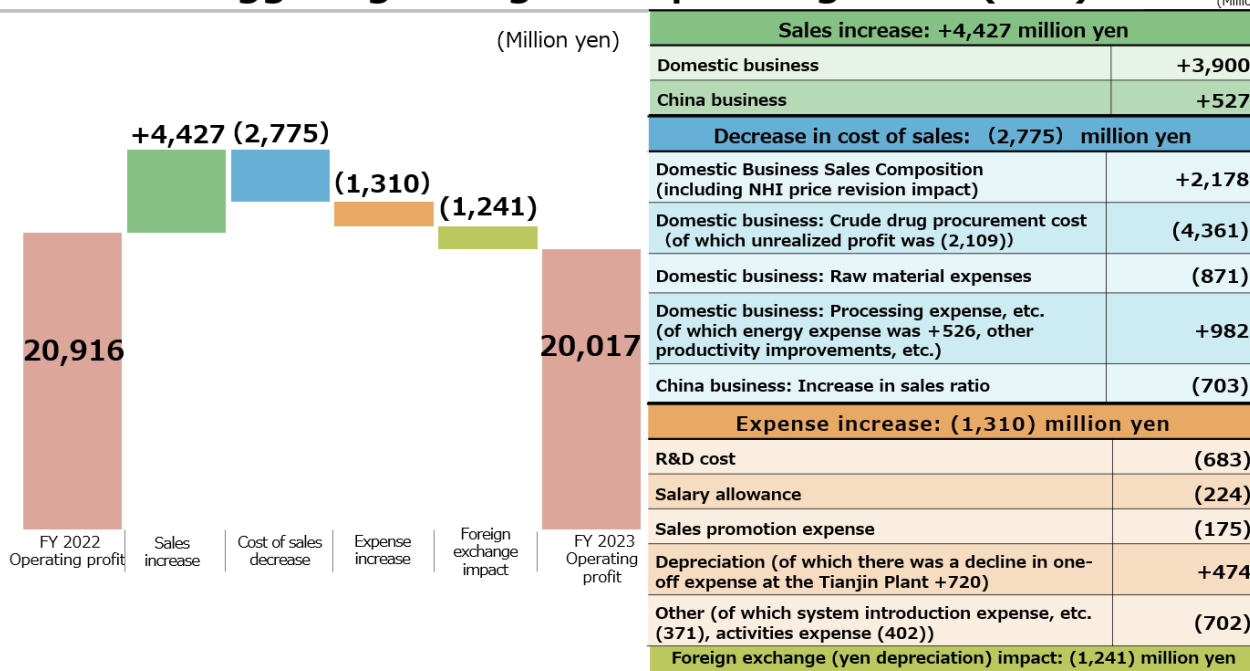
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Factors Triggering Changes in Operating Profit (YoY)



(Million yen)



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Factors behind the increase or decrease in operating profit compared to the same period last year. I will explain only the key points.

Operating profit was JPY20 billion, a decrease of JPY0.9 billion from the same period last year. The impact of the sales increase was a positive JPY4.4 billion. The breakdown is as follows: domestic business: plus JPY3.9 billion, and China business: plus JPY0.5 billion.

The impact of the increase in cost of sales was a negative JPY2.7 billion. The improvement was JPY2.1 billion due to changes in the sales mix, including the impact of the NHI drug price revision. Although there was a JPY900 million improvement in processing costs due to lower energy costs and improved productivity, crude drug procurement costs resulted in a negative factor of JPY2.2 billion due to higher unit prices for some crude drugs, mainly wild herbal medicines. In addition, the resumption of operations of some production lines at the Shanghai plant, which had been suspended due to renovation work, and an increase in unrealized income due to the start of shipments at the Tianjin plant resulted in a negative factor of JPY2.1 billion. The total was minus JPY4.3 billion. The impact of high raw material costs, such as lactose and packaging materials, was a negative factor of JPY0.8 billion.

The impact of the increase in expenses was a decrease of JPY1.3 billion. A decrease of JPY0.6 billion due to an increase in R&D expenses and a decrease of JPY0.3 billion due to an increase in expenses related to system implementation. Foreign exchange impact was a decrease of JPY1.2 billion. This is mainly due to the impact of higher import costs of crude drugs caused by the depreciation of the yen.

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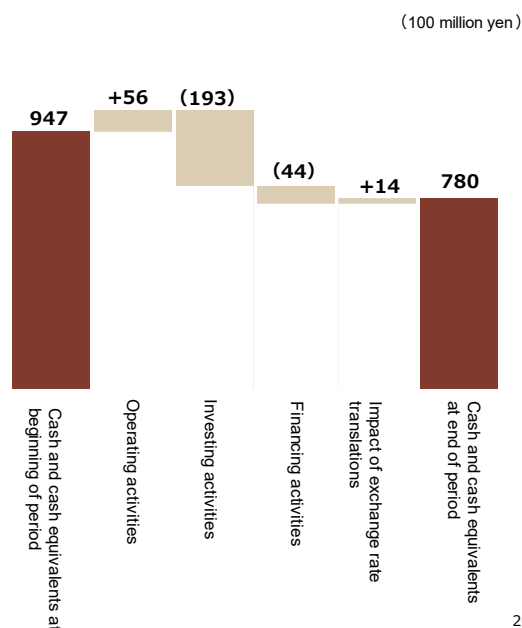
Financial Condition/Cash Flow Position for FY 2023



(Million yen)

	FY 2022 (March 2023)	FY2023 (March 2024)	Change
Total assets	396,813	428,254	31,440
Current assets	268,320	281,292	12,971
Non-current assets	128,492	146,961	18,469
Total liabilities	124,566	132,889	8,322
Current liabilities	47,205	68,557	21,352
Non-current liabilities	77,361	64,332	(13,029)
Total net assets	272,246	295,364	23,118
Equity ratio	63.5%	63.2%	(0.3)pt

	FY 2022 (March 2023)	FY2023 (March 2024)	Change	Of which, Exchange rate
Inventories	101,726	117,617	15,889	589
Merchandise and finished goods	11,257	12,139	881	290
Work in process	14,430	18,309	3,878	142
Raw materials and supplies	76,038	87,168	11,130	156



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Financial position and cash flow. I will explain only the key points.

Current assets increased by JPY12.9 billion. The main breakdown is an increase in inventories due to increased sales of JPY15.8 billion, including JPY3 billion due to foreign exchange factors, and a decrease in cash and deposits of JPY16.6 billion.

Fixed assets increased by JPY18.4 billion. The main breakdown is an increase of JPY8.9 billion in capital investment for the construction of the Tianjin plant and JPY2.8 billion in system-related investment for the renewal of IT infrastructure. The increase in current liabilities and decrease in long-term liabilities were mainly due to the transfer of JPY15 billion bonds from long-term to short-term due to their redemption within 1 year.

The equity ratio declined 0.3 percentage points to 63.2%. Cash flows are shown in the waterfall graph to the right.

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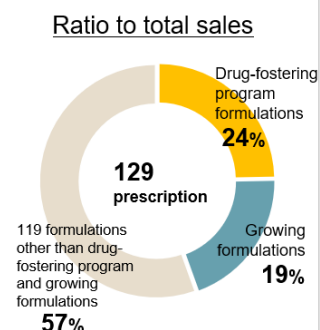


Domestic Business : Sales of Drug-fostering Program Formulations/Growing Formulations



(Million yen)

	Net sales Ranking	Product No./formulation name	FY 2022	FY 2023	YoY	
Drug-fostering program formulations	1	100 Daikenchuto	9,739	9,851	+111	+1.1%
	3	43 Rikkunshito	7,300	7,454	+153	+2.1%
	4	54 Yokukansan	7,380	7,447	+66	+0.9%
	9	107 Goshajinkigan	3,421	3,698	+276	+8.1%
	24	14 Hangeshashinto	1,390	1,448	+57	+4.2%
Total sales for drug-fostering program formulations			29,233	29,899	+666	+2.3%
Growing formulations	2	41 Hochuekkito	7,727	7,956	+228	+3.0%
	5	17 Goreisan	6,208	6,869	+660	+10.6%
	6	24 Kamishoyosan	5,050	5,117	+66	+1.3%
	17	108 Ninjin'yoeito	2,128	2,305	+177	+8.3%
	18	137 Kamikihito	2,067	2,290	+223	+10.8%
Total sales for growing formulations			23,182	24,539	+1,356	+5.9%
Total sales for 119 formulations other than drug-fostering program and growing formulations			66,946	71,918	+4,971	+7.4%
Total sales for 129 prescription Kampo products			119,362	126,357	+6,994	+5.9%



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These are sales by domestic prescription Kampo products for "drug fostering" program formulations and "growing" formulations.

Sales of 129 prescription Kampo products totaled JPY126.3 billion, an increase of 5.9% over the same period last year. Sales of "drug fostering" program formulations grew 2.3% YoY, and sales of "growing" formulations grew 5.9% YoY, led by Goreisan, Ninjin'yoeito, and Kamishoyosan.

Sales of Goreisan grew due to information provision activities in line with the needs of patients with circulatory problems, headaches and dizziness, Ninjin'yoeito for anorexia associated with frailty in the elderly, and Kamishoyosan for mental anxiety and insomnia.

Sales of other 119 prescriptions grew 7.4% YoY to JPY71.9 billion due to increased demand, especially for cold-related prescriptions.

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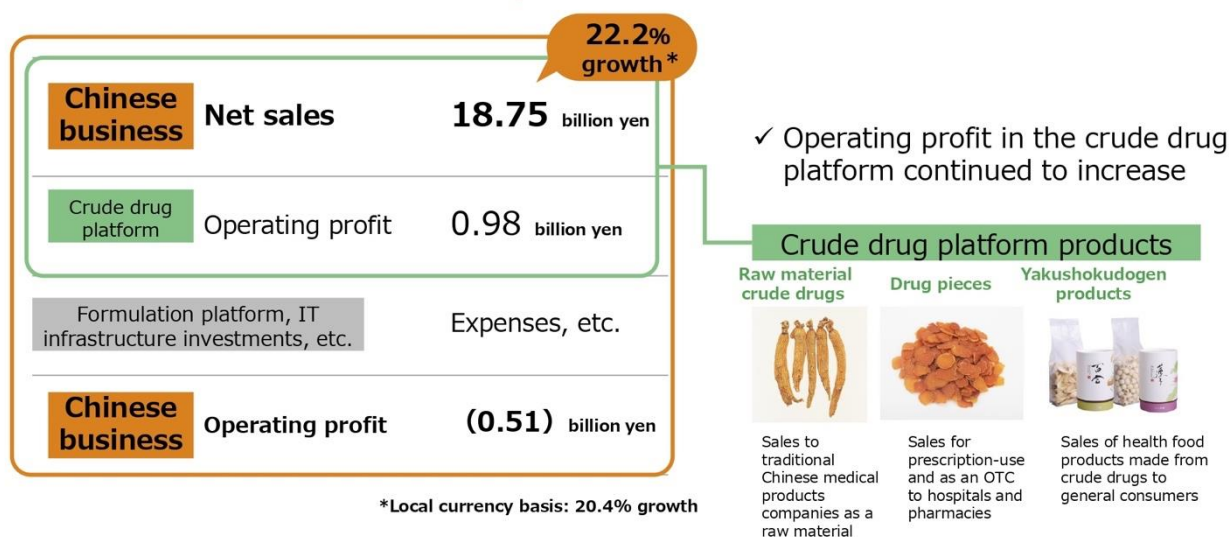
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China Business: Crude Drug Platform Business Sales Expansion

By expanding sales of Crude Drug Platform , we have achieved our business plan in China.



22

Next is the status of our China business.

Sales of the China business achieved the sales plan for the China business, growing 22.2% YoY to JPY18.7 billion, thanks to expanded sales, mainly of raw material crude drugs. Operating profit from the crude drug platform continued to grow to JPY900 million.

FY 2024 Earnings Forecast

Forecast of increased sales and profit /First MediumTerm Management Plan is expected to achieve its numerical targets

[Million yen]	FY 2023 Results	FY 2024 Earnings Forecast	YoY	
			Amount	Change
Net sales	150,845	185,000	+34,154	+22.6%
Domestic business	132,099	163,400	+31,300	+23.7%
China business	18,745	21,600	+2,854	+15.2%
Operating profit	20,017	39,500	+19,482	+97.3%
Domestic business	20,531	39,490	+18,958	+92.2%
China business	(514)	10	+524	—
Ordinary profit	23,493	39,500	+16,006	+68.1%
Profit attributable to owners of parent	16,707	28,500	+11,792	+70.6%
Income statement exchange rate (JPY/RMB)	19.83	21.00	+1.17	—
ROE	6.4%	10.0%		
EPS	219.83円	375.35円		

First Medium-Term Management Plan Numerical targets (fiscal 2024)

Net sales:
¥162.0billion
Operating profit:
¥29.0billion
ROE: 8%

Versus the First Medium-Term Management Plan
Although there was negative impact from a rise in a portion of crude drug expenses, mainly wild crude drugs, a depreciation in the yen's value against major currencies, and ongoing high expenses for raw materials and energy, we expect to achieve all our indicators (sales, operating profit, ROE) in the First Medium-Term Management Plan owing to a boost in drug prices reflecting the recalculation of unprofitable products

(Note) · Foreign exchange impact (non-operating profit) was not factored into the earnings forecast given the difficulty to reasonably calculate this impact based on the status of the forex market.

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 Asia's Meetings, Globally

18

Next, I would like to explain our forecast for FY2024.

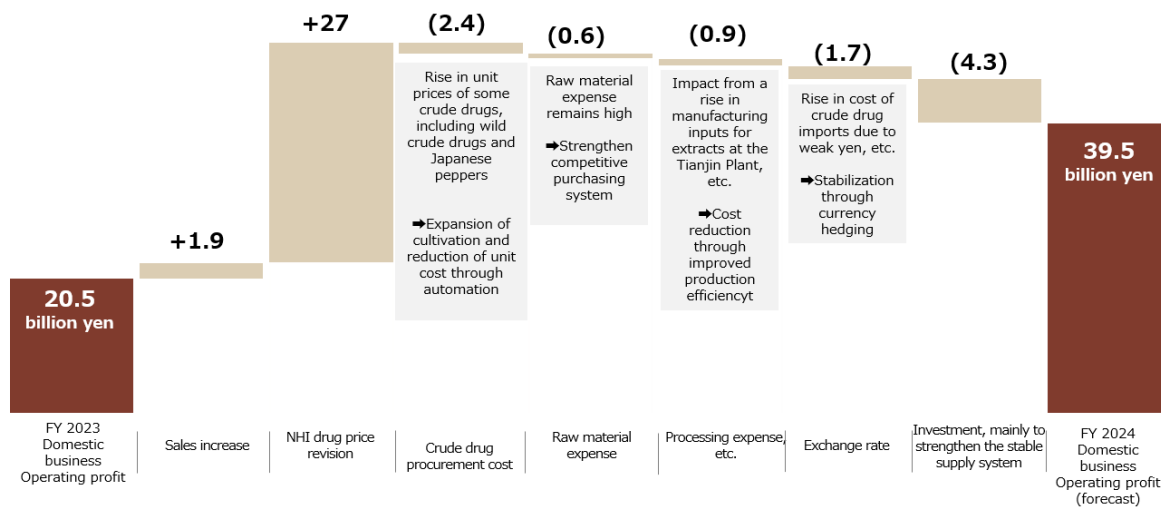
We expect to increase revenues and profits in FY2024. Sales total JPY185 billion, with JPY163 billion coming from the domestic business and JPY21 billion from the China business. Operating profit is expected to be JPY39.5 billion, and the China business is planned to be profitable from the current fiscal year. Ordinary profit is projected at JPY39.5 billion, profit attributable to owners of parent at JPY28.5 billion, ROE at 10%, and EPS at JPY375.35.

In comparison with the numerical targets of the first medium-term management plan, we expect to achieve all numerical targets due to the increase of NHI prices by price re-evaluation as money-losing products, etc., although cost of sales was much higher than initially expected due to the increase in unit prices of some crude drugs, mainly wild crude drugs, the weak yen, and high raw material and energy costs.

FY 2024: Factors Triggering Changes in Operating Profit in the Domestic Business



- Although factors in the external environment, including inflation, continue to be harsh, we look for profit growth owing to NHI drug price revisions (recalculation of unprofitable products)
- Plan to implement investment, mainly to strengthen the stable supply system



This is an analysis of the factors contributing to the increase or decrease in operating profit forecast for domestic business in FY2024.

Higher gross profit due to higher sales in the domestic and China business will lead to a JPY1.9 billion increase, and NHI drug price revision due to the application of price re-evaluation as money-losing products will lead to an increase of JPY27 billion.

In response to the impact of the external environment, as indicated by the arrows at the bottom of the items in the waterfall graph, we are working on various initiatives to reduce costs, a typical example being the expansion of cultivation of crude drugs and automation using AI technology, and the results of these initiatives are beginning to be seen. However, the cost of procuring crude drugs will increase due to higher unit prices of certain crude drugs such as wild crude drugs and Japanese peppers, which will lead to a decrease of JPY2.4 billion.

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We expect a decrease of JPY0.6 billion due to the impact of high raw material costs, a decrease of JPY0.9 billion due to energy costs and the impact of increased production input of extract powder at the Tianjin plant, which has a high cost ratio in the initial stage of operation, and a decrease of JPY1.7 billion due to the impact of yen depreciation on imports of crude drugs.

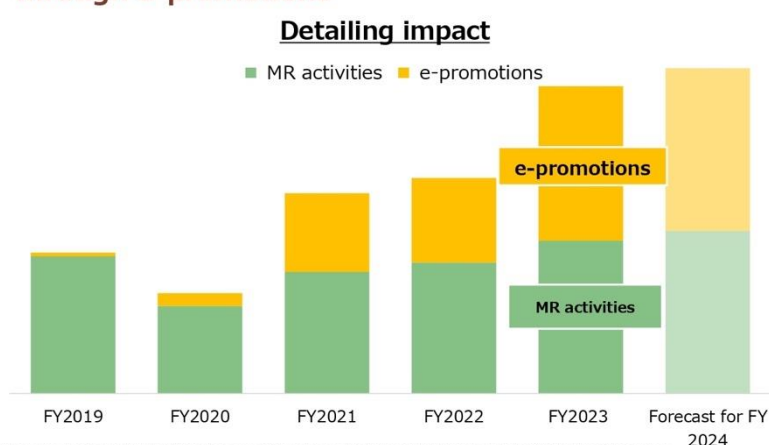
A decrease in profit of JPY4.3 billion YoY due to further strengthening of the stable supply system and other factors. The main breakdown is JPY2.5 billion for strengthening the stable supply system and JPY0.8 billion for DX-related investments.

The Status of Expansion for Information Provision Activities



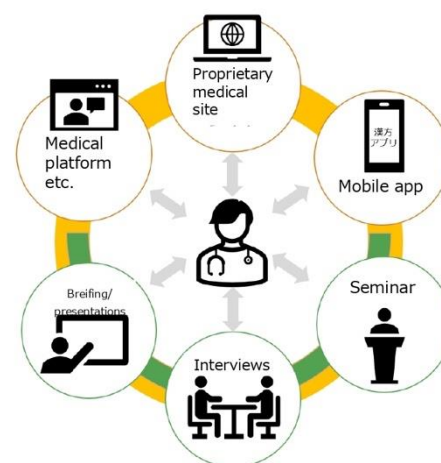
In FY 2023, detailing impact rose 140% versus the previous year, in particular e-promotion growth was up 180%

In FY 2024, we plan to further expand information provision activities, mainly through e-promotions



*Number of cases of detailing impact: Number of cases of information recognition from various channels, including MR activities and the Internet
 *e-promotions: Information provision, mainly through online lectures and video streaming
 *MR activities: Information provision via MRs + in-person lectures

INTAGE Healthcare Inc. survey, Impact Track



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This is the status of the expansion of the volume of information-providing activities in the domestic business.

In FY2023, detailing impact, the number of information recognition, increased 40% from the previous year. The Company strengthened its system for delivering information tailored to individual doctors by expanding the content of its medical website and upgrading its marketing automation system, etc. As a result, e-promotion increased significantly by 80% YoY.

In terms of e-promotion, which has been strengthened to date, the organization in charge will be upgraded to the Kampo DX Promotion Department in FY2024, and we aim to increase the detailing impact by promoting information provision activities through further functional expansion.

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Domestic business: Trends in the Number of Physicians Writing 10 or More Prescriptions for Kampo Pharmaceuticals

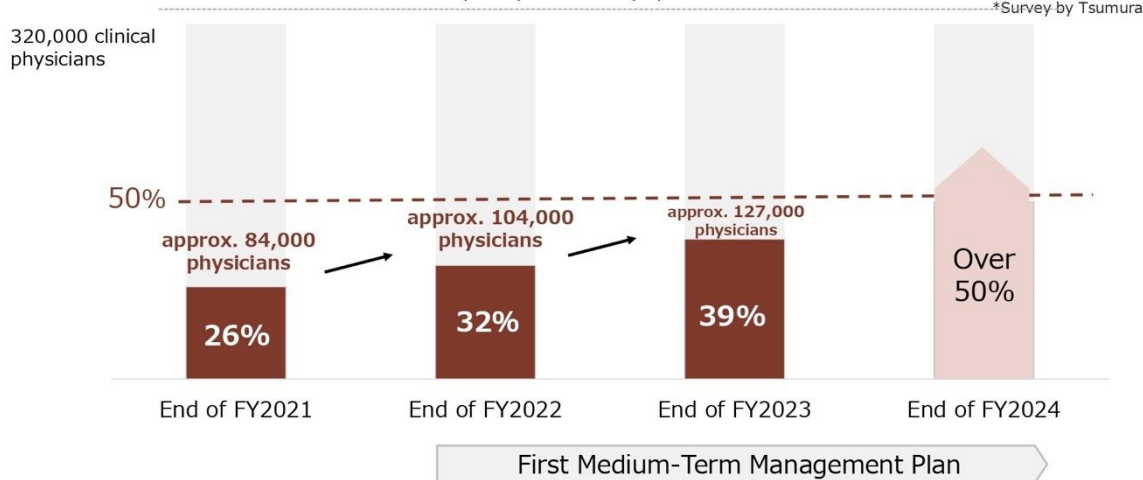


The number of physicians writing 10 or more prescriptions for Kampo pharmaceuticals increased by approximately 23,000 physicians, a ratio of 39%

Aim to achieve a ratio of 50%-plus, owing to the implementation of hybrid promotions

*Trend in the number of physicians writing 10 or more prescriptions for Kampo pharmaceuticals

*Survey by Tsumura



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The number of physicians prescribing 10 or more prescription Kampo formulations.

The number of physicians prescribing 10 or more Kampo formulations increased by approximately 23,000 during the year, reaching 127,000 at the end of FY2023. The percentage is 39% of the total.

In clinics and physician offices, more than 60% of physicians are prescribing 10 or more Kampo formulations, but in hospitals, less than 50%, so we will increase contact opportunities by expanding e-promotion. We will work to achieve a medical practice where at least 1 out of 2 physicians will be a physician prescribing 10 or more Kampo products.

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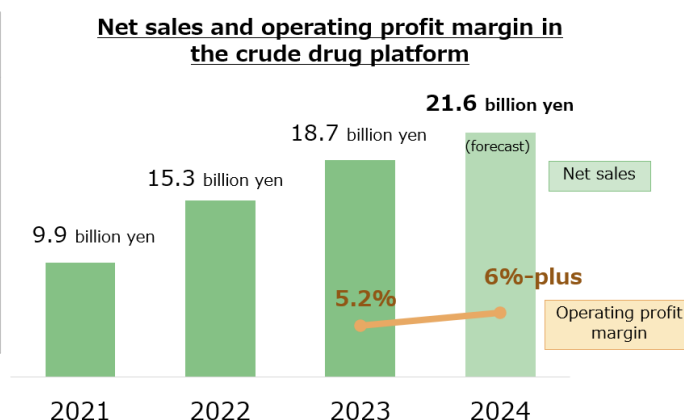


- In the crude drug platform, we estimate sales CAGR of 30%
- In FY 2024, we plan an improvement in the operating profit margin owing to an expansion in scale that focuses on profitability

Crude drug platform policy

“Expand scale focusing on profitability”

- Emphasis on improving profit margins
- Expand sales mainly to business partners that recognize the value of high quality



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The China business as a whole will be profitable in terms of operating profit.

In the first medium-term management plan, the crude drug platform is targeting a sales CAGR of 30%, which is expected to be achieved. For FY2024, we aim to achieve an operating margin of 6% or more by focusing on improving profit margins and expanding sales, especially to customers who recognize the value of our high quality.

Until FY2023, various expenses, including investments in the formulation platform infrastructure, exceeded the operating profit of the crude drug platform, resulting in a loss for the China business as a whole, but in FY2024, an increase in the operating profit of the crude drug platform will bring the overall China market into the black.

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- Accelerate the bolstering of production capacity, Improved productivity through automation, newly establish a warehouse, etc.

Capex
34.0 billion yen

*Approx. +15.0 billion yen YoY

Main investment activities	Total investment	FY 2024 investment amount	Period
Tianjin Plant Phase 2 and Phase 3 construction (Manufacturing of Kampo powdered extracts)	25.0 billion yen	9.5 billion yen	FY 2021 - FY 2026
Newly establish a manufacturing process for Kampo powered extracts, and a granulation packaging process	68.0 billion yen	10.5 billion yen	FY 2024 - FY 2027
Yubari Tsumura Expand a crude drug warehouse	2.5 billion yen	1.5 billion yen	FY 2023 - FY 2025



- Additional manufacturing costs

Expense:
+2.5 billion yen YoY

Main activities	FY 2024 increase in value
Hike headcount to newly establish manufacturing line, etc.	+1.0 billion yen
Strengthen prevention and maintenance, secure warehouse, etc.	+1.5 billion yen



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We will invest to further strengthen our stable supply system, which is one of the objectives of the NHI drug price revision in FY2024.

This investment will not be completed in a single year, but we will continue to make the necessary investments in FY2025 and beyond. Today, we will explain the specifics for FY2024, and the details for FY2025 and beyond will be presented in the second medium-term management plan to be released next fiscal year.

In FY2024, we plan to invest JPY34 billion in tangible fixed assets, up JPY15 billion from the previous year, to accelerate production capacity expansion, improve productivity through automation, and build new warehouses. The first of these is the second and third phases of construction at the Tianjin plant, which has been underway for some time. The total investment is JPY25 billion, with JPY13 billion invested by FY2023 and JPY9.5 billion planned for FY2024.

Next, as a new major investment, we will increase the capacity of the manufacturing process for Chinese Kampo extract powder and its downstream process, the granulation and packaging process. The total investment is JPY68 billion, with JPY10.5 billion to be invested in FY2024.

And in order to increase the amount of crude drug inventory stored in Japan in response to increased production, Yubari Tsumura will expand its crude drug warehouse. The total investment is JPY2.5 billion, with a planned investment of JPY1.5 billion in FY2024.

An additional JPY1.5 billion is also projected for strengthening preventive maintenance, etc. We will continue to invest in further strengthening our stable supply system to support the expansion of the Kampo market.

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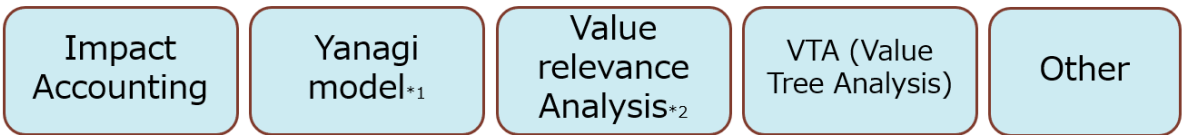
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- (1) Value of pharmaceutical products derived from natural ingredients
- (2) Value in the Kampo value chain
- (3) Value of the organization and human capital

Approach for Visualization Using an Optimal Analytic Method



*1: Model developed by Ryohei Yanagi employed in the "CFO Policy (CHUOKEIZAI-SHA HOLDINGS, INC. 2020)"
 *2: One analytic method in Digital ESG Data Analytics of ABEAM Consulting Ltd.

Next, I would like to discuss the concept of pre-financial capital and corporate value enhancement.

In our Integrated Report, we present a seven-capital value creation cycle, including organizational capital, in addition to the six capitals of the International Integrated Reporting Framework. We are working to visualize how our efforts in each of the six invisible capitals, other than financial capital, will lead to future financial value, to gain a better understanding of these capitals, and to clarify issues in these efforts and promote improvements.

We hope to contribute to the health of even more people by providing an easy-to-understand understanding of the value of pharmaceuticals derived from natural ingredients, including their multi-component nature and indications for integrative medicine.

We would also like to approach the value in the Kampo value chain, for example, the cultivation of crude drugs with controlled safety and quality through our proprietary GACP, and the value of our organization and human capital, which are the foundation of our company, through analytical methods that have been developed and focused on in recent years.

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Initiatives for the visualization of the relevance of pre-financial capital and corporate value improvement



Goal: Visualization of the relevance of initiatives related to pre-financial capital and the corporate value improvement
Analyze issues through visualization to contribute to the improvement of initiatives

Analytic method: Overview (Yanagi model) analysis *1
• Value relevance analysis (Implement analysis: ABEAM Consulting Ltd., Digital ESG Data Analytics)

◆ Example of analysis: Results of overview analysis (excerpt)

Employment

◆ Promotion rate (female employees)
1% increase → PBR improved 0.27% after two years

Employee health

◆ Health checkup rate
1% increase → PBR improved 12.72% after three years

Work-life balance

◆ Paid leave acquisition rate (All employees)
1% increase → PBR improved 7.37% after two years
 ◆ Average number of days of childcare leave taken (female employees)
1% increase → PBR improved 1.25% after one year
 ◆ Average period of childcare leave taken (female employees)
1% increase → PBR improved 0.28% after two years

Implemented the aforementioned analysis (overview analysis/value relevance analysis) in FY2023. In the overview analysis, confirmed items with a positive correlation to pre-financial capital and PBR. Implementing a detailed analysis of the results. In accordance with the analytical results, extract issues from each initiative to contribute to improvements. Results of detailed analysis is scheduled to be disclosed. Plan to continue to implement this analysis.

*1: Analysis using the ABEAM Consulting Ltd. Digital ESG Platform in accordance with the model developed by Ryohei Yanagi based on the "CFO Policy (CHUOKEIZAI-SHA HOLDINGS, INC. 2020)"

As a first step toward the initiatives I just mentioned, in FY2023, ABeam Consulting's Digital ESG Data Analytics conducted a bird's eye view analysis and value relevance analysis of our pre-financial capital initiatives.

The overarching analysis analyzes the correlation between indicators and PBR in ESG activities. In this case, we collected and analyzed data on 502 indicators, and as a result, significant and desirable correlations with PBR were detected in 36 indicators.

We are currently in the process of conducting a detailed internal analysis of the results, and I have presented some of these results on the slides today. We will prepare to disclose the results of the detailed analysis and the issues and improvement measures extracted from the analysis in our future integrated reports and other documents.

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ROE Improvement: Quickly Realize a Positive Equity Spread Early On and Expand



Announced on November 7, 2023



*Cost of equity: approx. 7%

Calculate using the CAPM Risk free rate: 2%; Risk premium: 6%, β value: approx. 0.8

*Equity spread = ROE – Cost of equity

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Finally, I would like to update you on our capital policy.

We started in-house management using ROIC at the beginning of the first medium-term management plan, and are working on business management that contributes to corporate value enhancement, after setting KPIs corresponding to profitability improvement, balance sheet improvement, etc.

In addition to those, and this is what we presented on November 7, 2023, we will accelerate our efforts to address each of these issues by breaking them down into profitability, asset turnover, and financial leverage. Under this policy, we will explain our efforts in FY2024 on the next page and beyond.

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Improved B/S by curtailing the collection site for accounts receivables and decreasing cross-shareholdings



Curtail the collection site for accounts receivables

Negotiate with business partners on collection sites for accounts receivables and

Reduce in stages by approximately 20%



Decrease cross-shareholdings

Based on a policy with a principle of zero

From FY 2024, aim to realize full-fledged reduction and cut by half early on

*Excluding shares with a purpose of forming a capital and business alliance

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This is a specific balance sheet improvement initiative to improve capital efficiency.

We will improve our balance sheet and capital efficiency by shortening the accounts receivable collection period and reducing strategic stock holdings. We are negotiating with pharmaceutical distributors and wholesalers to shorten the collection period for accounts receivable, aiming to shorten the period by 20% in stages from the current level.

We have been gradually reducing our policy shareholdings through ongoing negotiations with our counterparties, but under the policy of zero shareholdings in principle, we will achieve a full-scale reduction starting this fiscal year, aiming to halve the number of shares held as soon as possible.

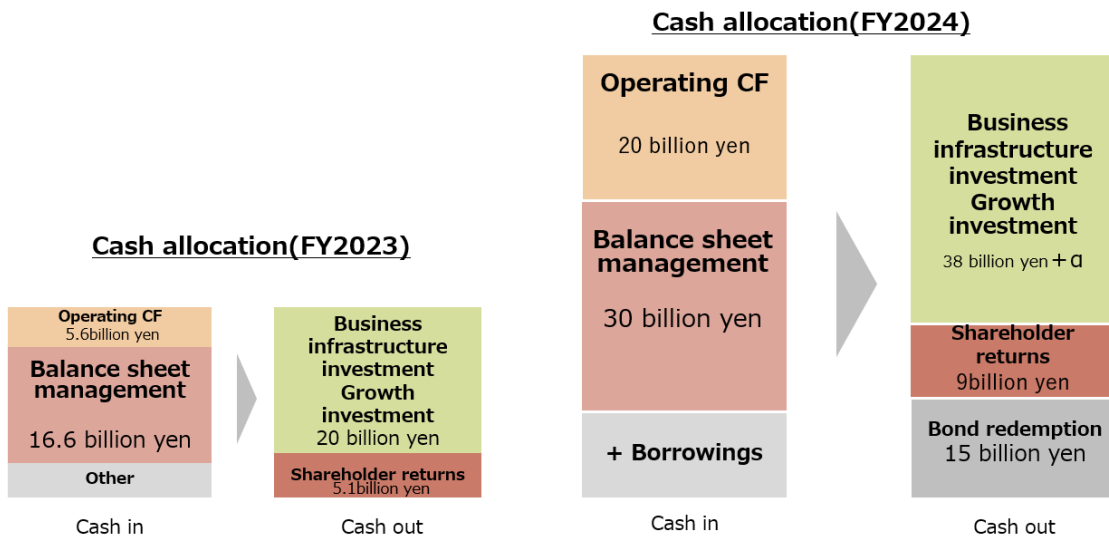
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Cash allocation

In addition to the Operating CF, create cash by improving the balance sheet, and allocate to the further growth of shareholder returns and business operations



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Cash allocation for FY2024.

In addition to operating cash flow, cash is generated through balance sheet management and allocated to shareholder returns and further business growth. Cash inflow is expected to be JPY20 billion from operating cash flow and JPY30 billion from balance sheet management, including CCC improvement, reduction of cash on hand, and reduction of policy shareholdings.

Borrowings will be funded appropriately from time to time while confirming the level of cash and deposits on hand and funding needs. Cash outflows are expected to be more than JPY38 billion for business infrastructure and growth investments, JPY9 billion for shareholder returns, and JPY15 billion for the redemption of bonds scheduled for the end of May.

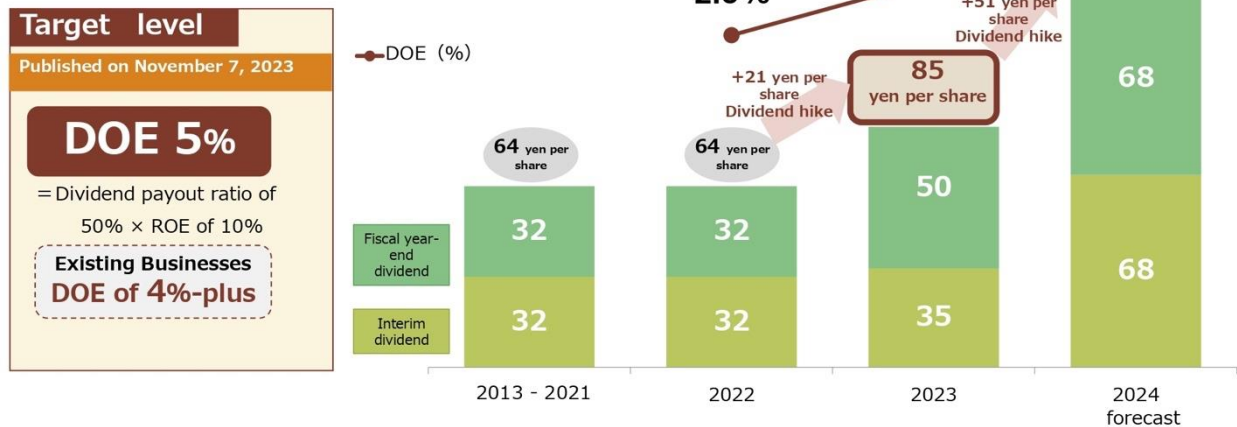
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Shareholder returns

- In FY 2023, per-share dividend hiked to 85 yen
- In FY 2024, we expect to payout a dividend of 136 yen in accordance with the shareholder return policy
- Aim for the realization of a DOE of 5%



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Finally, shareholder returns.

As for the dividend for FY2023, we have increased the dividend by JPY15 per share from the most recent dividend forecast to JPY85 per share for the full year, since net profit for the year exceeded our forecast. DOE will be 2.5%.

We consider the return of profits to shareholders as an important policy of the Company and have paid an annual dividend of JPY64 per share for 10 years from FY2013 to FY2022, based on the principle of maintaining stable dividends.

On November 7, 2023, as part of our efforts to enhance corporate value over the medium to long term toward the realization of TSUMURA VISION "Cho-WA" 2031, we announced revisions to our basic capital policy and shareholder return policy with the aim of further enhancing shareholder returns while maintaining a balance between maintaining financial soundness and investing in growth under management based on balance sheet management.

Based on this policy, I have told you that in FY2023, we will increase the dividend by JPY21 per share from the previous year to JPY85 per share for the year. Based on the earnings forecast and shareholder return policy explained to you, we will increase the dividend for FY2024 by JPY51 per share, to a projected annual dividend of JPY136 per share. The dividend payout ratio will be 36.2% and DOE will be 3.6%.

We will also continue to make investments that contribute to the sustainable expansion of our domestic business and the growth and foundation building of our China business, thereby accelerating our efforts to enhance our medium- and long-term corporate value and achieve our target level of DOE of 5%.

That concludes my explanation.

Kitamura: Thank you very much. Finally, Mr. Kaneko will explain the progress of development in the United States. Please begin.

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1. Complete Patient Enrollment for the Late Phase II Trial for TU-100
2. Tackle TU-100 US Development
3. Outlook Going Forward

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Kaneko: My name is Kaneko, International Pharmaceutical Research & Development Division. Thank you very much for your participation today.

We are pleased to announce the completion of patient enrollment for the late stage Phase II study of TU-100, in the United States, which we are working on.

Today, I will be speaking in three parts.

1-1. Summary and Trends for the TU-100 Trial



<https://clinicaltrials.gov/ct2/show/NCT04742907?term=TU-100&cntry=US&draw=2&rank=7>

Target disease: Postoperative ileus (POI)

Trial format: Multi-center, randomized, double-blind, placebo-controlled trial

Target cases: 402 cases

Group structure: 15g/day group, 7.5g/day group, placebo group

Patient enrollment period: July 2021 - March 2024 (Two years and eight months)

Main endpoints: Recovery time for gastrointestinal functions

The COVID-19 pandemic broke out in and after 2020. And given that rivals halted and/or suspended development,

we completed patient enrollment with a target sample size of 402 cases in March 2024!

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First, I will report the completion of patient registration.

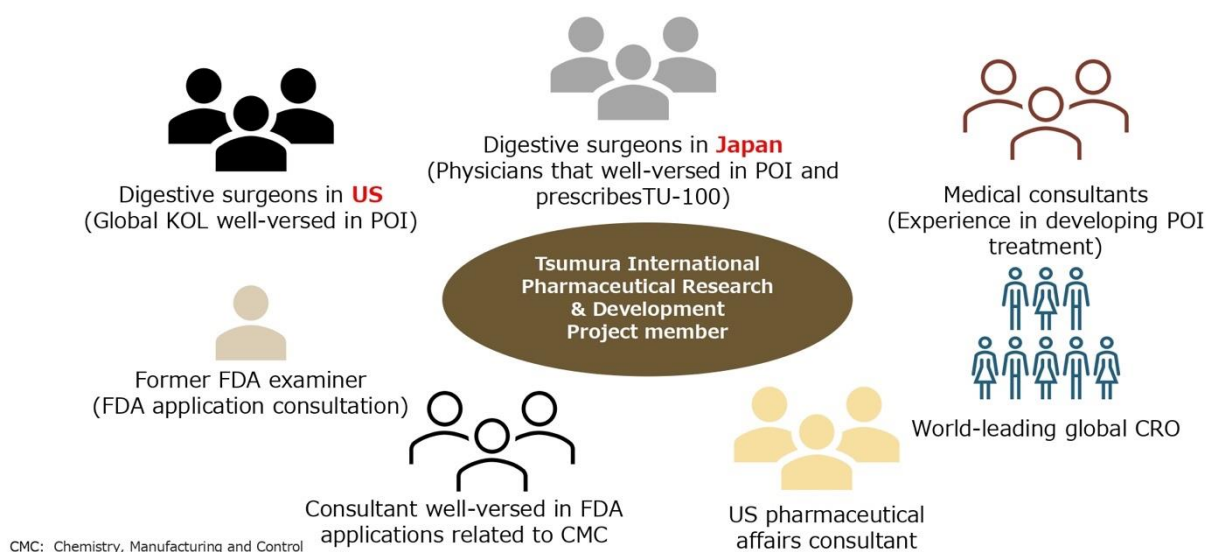
The target disease for this clinical trial is postoperative ileus. Hereafter abbreviated as POI. The trial format is a multicenter, randomized, double-blind, placebo-controlled trial with a target number of 402 patients in a late phase II study.

The COVID-19 pandemic broke out in and after 2020 and at the start of this trial, patient enrollment was not as high as expected, making it a challenge in a harsh environment. While our competitors in POI drug development have either discontinued or suspended their trial, we have completed the patient enrollment period as shown here, and have completed the enrollment of the target number of 402 patients in our trial by March 2024.

1-2. TU-100 US Development System



Proceed as an amazing "single team"



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The clinical protocol for this trial was developed in collaboration with gastroenterological surgeons in Japan and the US who are familiar with the pathogenesis of POI and have agreed to support the development of TU-100 in the US. The trial is being conducted with the clinical trial advice of a medical consultant team with experience in the development of drugs for POI. As this slide shows, we are also progressing through numerous other cooperation and support, forming an amazing single team.

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1-3. Initiatives for the TU-100 Trial



Multi-center, randomized, double-blind, placebo-controlled trial, being participated in by 43 medical centers in the US



Direct and detailed communication with centers participating in the trial



Execute under a strict safety management system by setting up a data safety monitoring committee



Secure Kampo formulation manufacturing management technology and reliability to minimize lot-to-lot variation
Provide a placebo drug that utilizes the same manufacturing knowhow

Reconfirm medical needs to treat POI and expectations in herbal medicines

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43 medical facilities across the US participated in the trial. Our direct and attentive communication with the sites participating in the clinical trial allowed us to reaffirm their expectations for the botanical drugs and their medical needs for postoperative ileus.

In addition, in order to ensure the safety of the subjects, we proceeded with this clinical trial under a strict safety control system. And although it was not easy to manufacture placebo drugs for Kampo medicines, we were able to deliver the actual drugs and placebo drugs to the clinical trial sites without delay by investing in our technology. These achievements give us great confidence as we move forward with our overseas expansion.

2-1. Origin of TU-100 US Development



In the US, domains in which the use of Western drug treatment is a difficult, we aim to help treatment for US patients through the development of Kampo formulations that will have a specific effect for diseases!



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Next, I would like to explain the background of the TU-100, our target areas, and peripheral information on the TU-100, titled "Tackle TU-100 US Development."

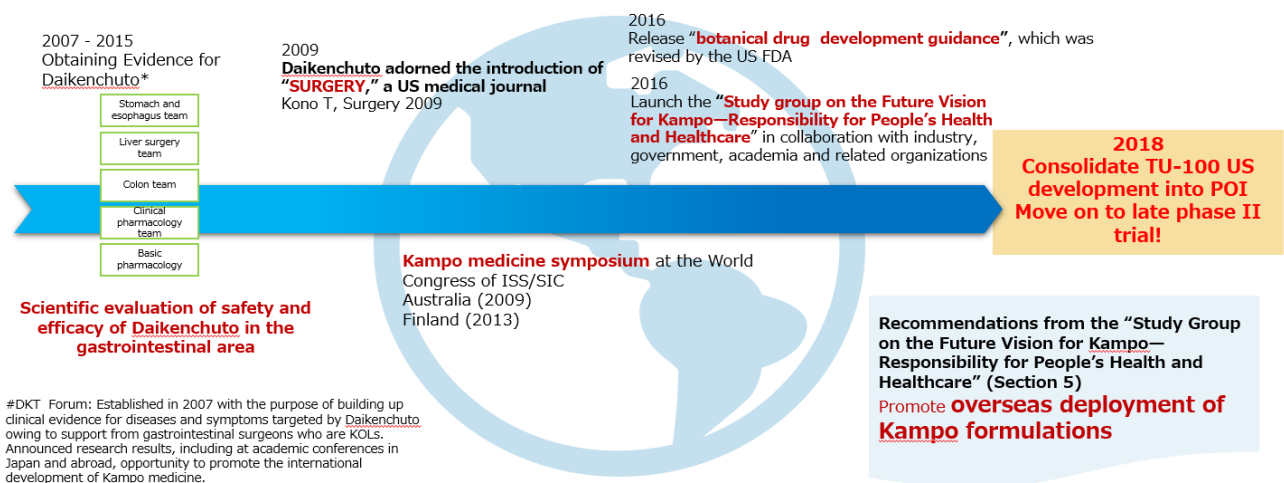
First of all, this slide shows the origin of the TU-100 US development.

Our goal is to help treat US patients through the development of diseases in which Kampo products may be specifically effective in areas that are difficult to treat with Western medicines in the United States.

2-2. History of TU-100 US Development



Going from unscientific to scientifically verified



#DKT Forum: Established in 2007 with the purpose of building up clinical evidence for diseases and symptoms targeted by Daikenchuto owing to support from gastrointestinal surgeons who are KOLs. Announced research results, including at academic conferences in Japan and abroad, opportunity to promote the international development of Kampo medicine.

Boost the degree of international focus on Kampo medicines

The history of TU-100 US development is a long one. The Japanese gastrointestinal surgical KOLs spearheaded the evidence acquisition research activities for Daikenchuto that began in 2007, which resulted in comprehensive findings to obtain clinical evidence for Daikenchuto in various gastrointestinal fields. This has now provided the impetus to strongly promote the development of TU-100 in the United States.

In addition to triggering a variety of events as shown here, the Proposal 5 of the Study Group on the Future Vision for Kampo—Responsibility for People's Health and Healthcare, which was established in collaboration with industry, government, academia, and related organizations, includes the phrase "promotion of overseas deployment of Kampo products."

The FDA, the US regulatory authority, issued a revised botanical drug development guidance in 2016. We are using this guidance as a bible for our US development, and I will discuss this guidance in detail in the following slides.

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POI (Postoperative ileus) is an unmet medical need

POI is a

- Pathological condition that impairs the peristaltic action of the intestinal tract due to abdominal surgery
- There are main causal factors and the progression of the disease is complex

US market evaluation of POI medicines: US HCUP database

- **The probability of POI occurring is high in digestive system surgeries**
 Colectomy: 14.90%, other types of gastrointestinal resections: 18.63%
- **The number of digestive system surgeries to continue to increase going forward**

	2015	2019	2025
No. of surgeries with the potential of triggering POI	2.08 million	1.97 million	1.87 million
Portion of digestive system surgeries	730,000	750,000	770,000

- **The only treatment for POI is Alvimopan (μ-opioid receptor antagonist)**

This data are the results of an analysis implemented in 2021 based on IQVIA data and a survey. IQVIA assumes no responsibility for any impact brought about from the use of these results.

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First of all, this slide shows the results of our research on POI, which is our target disease, its pathogenesis, marketability in the US, and therapeutic agents.

POI is a condition in which peristalsis of the intestinal tract is impaired by abdominal surgery. There are multiple causes of the disease, or etiologies, and the onset and progression of the disease are very complex.

We regularly conduct direct interviews with medical research firms and gastroenterologists in the US and have come to the conclusion that this POI is an unmet medical need.

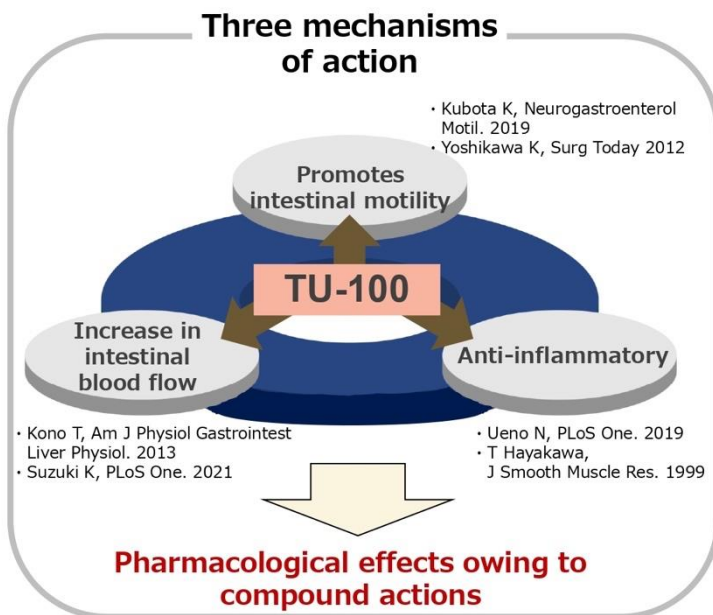
For example, even with today's increasing medical technology, the incidence of POI in gastrointestinal surgeries remains high, as shown in the figures here. The number of gastrointestinal surgeries will continue to increase, as shown in the table below.

And the only POI treatment approved by the US FDA is Alvimopan, μ-opioid receptor antagonist. In prescribing this medication, there is a risk of side effects such as myocardial infarction due to long-term use of the medication, and therefore, strict supervision is required.

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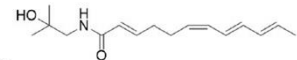
2-4. Unique Mechanism of Action of TU-100



- ✓ **Multi-component/multi-targeted drug therapy**
- ✓ **Enrich clinical and basic research**
- ✓ **Component crude drugs and main pharmacological ingredients**

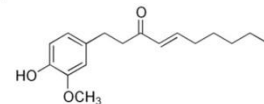
• Japanese peppers

hydroxy α -sanshool



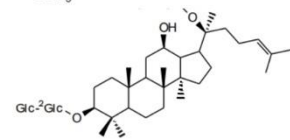
• Dried ginger

[6]-shogaol



• Ginseng

ginsenoside Rb₁



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In contrast, TU-100 is a multi-component, multi-targeted drug with multiple mechanisms of action, consisting of the three crude drugs shown on the right hand side of this slide: Japanese peppers, dried ginger, and ginseng.

As I mentioned earlier, POI is a complex condition with multiple etiologies, and the drug properties of TU-100, with its multiple mechanisms of action, are of interest to the physicians participating in this clinical trial and are one of the main reasons why they expect TU-100 to be clinically effective.

2-5. Transition in US FDA Botanical Drug Guidance

US FDA released the first edition of the “Botanical Drug Guidance” in June 2004

Guidance for Industry on Botanical Drug Products

Measures to promote the development of herbal/botanical pharmaceutical products after presenting clinical evidence on the same level as a small-molecule synthetic drug:

- Many herbal (botanical) drug manufacturers around the world applied for clinical trials and tackled development in the US
- Issues arise that are unique to the quality control and clinical evidence regarding herbal (botanical) medicine (product)

December 2016: Released a revised edition of the “Botanical Drug **Development** Guidance”

Botanical Drug **Development**: Guidance for Industry

Keyword: Totality of the Evidence

Regarding the ambiguity of safety and efficacy unique to botanical medicines (products), clarify evidence with respect to clinical evaluations, chemical/manufacturing management, management of raw material crude drugs, and biological quality control, and mutually request consistent management controls:

- **Promote development of botanical medicine (products) that fulfills the standardization of high quality**, naturally including those dealing with safety and efficacy

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Next, I would like to explain the evolution of the US FDA's Botanical Drug Guidance.

The FDA issued guidance in 2004, as written on top, to encourage drug manufacturers to develop botanical drugs. In response, many botanical drug manufacturers around the world took action to file clinical trial applications and US development challenges. At the same time, issues such as the difficulty of quality control unique to botanical drugs and the reproducibility of clinical evidence became apparent.

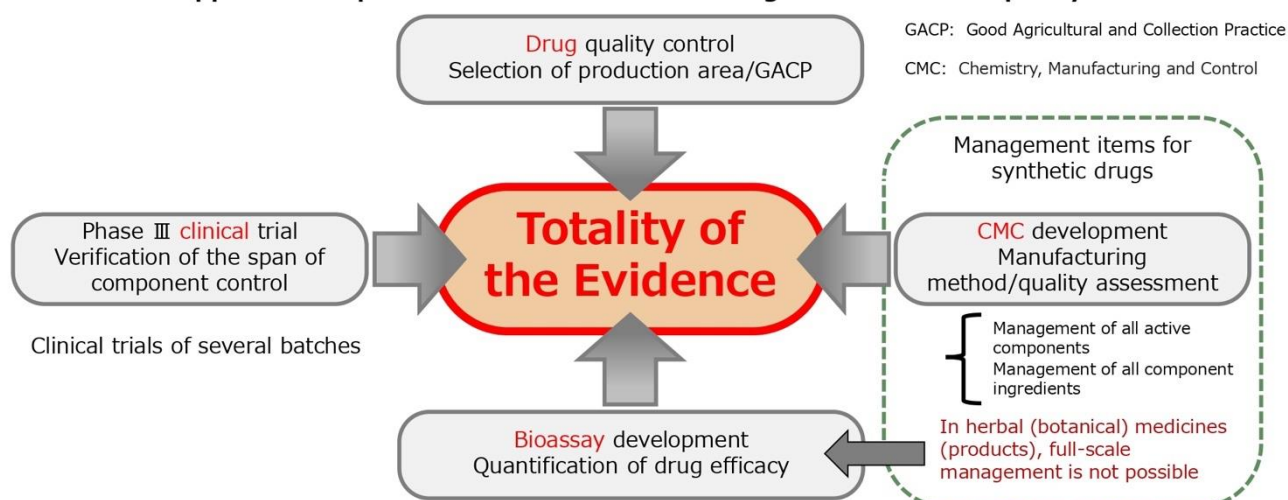
And in 2016, the FDA issued the revised guidance shown at the bottom of this slide. This was a specific concept of botanical drug development and development requirements. The key phrase is Totality of the Evidence, which requires the clarification of evidence from various aspects and a mutually consistent management system and coordination.

2-6. Development Requirements for Botanical Medicines (Products) Sought by the US FDA



Source: Revised Botanical Drug Development Guidance 2016 materials released by the US FDA

Approach unique to herbal medicines with large fluctuations in quality



Evaluate everything objectively/comprehensively, and derive highly reliable quality control methods

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Regarding totality of the evidence, please see this slide.

In the development of synthetic drugs, we develop compounds and CMCs that are limited to the synthetic drug control items shown on the right hand side. On the other hand, in botanical drugs such as Kampo medicines, it is not possible to control all identification at the component level because they are pharmaceuticals derived from natural ingredients.

Therefore, the FDA Instructions the use of multiple batches of clinical trials to control the range of variation in the control adjustment. For example, we are seeking to conduct PIII studies using multiple investigational drugs and batches by combining crude drugs from different production areas, etc., and to verify the breadth of ingredient control to ensure efficacy and safety with those results.

It also requires the development of bioassays that reflect clinical efficacy, i.e., quality control with biological tests, and the selection of the source for quality control of raw material crude drugs and GACP control.

In other words, as shown below, the key is to objectively and comprehensively evaluate everything and derive a reliable quality control method.

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What this slide will help you understand is that the quality control requirements for botanical drug development are much more diverse and involve more difficult challenges than those for synthetic drug development.

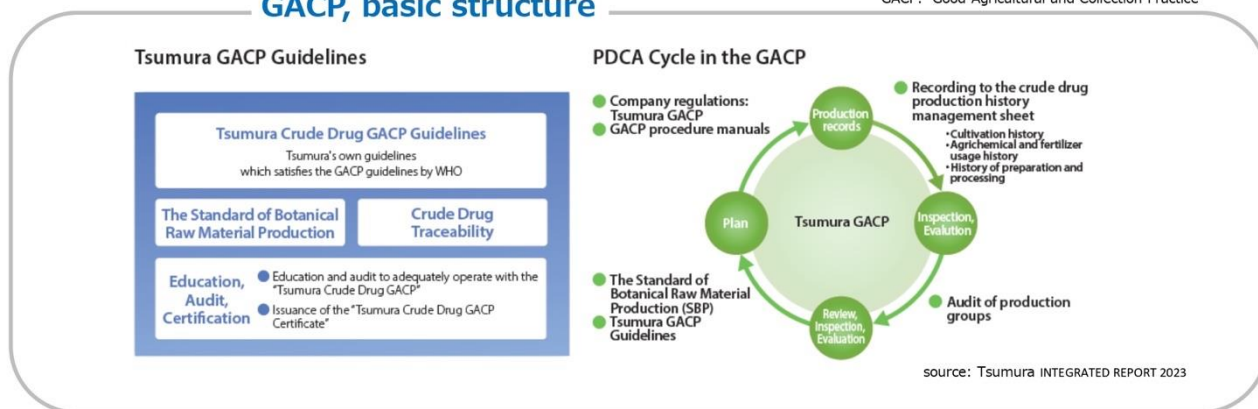
There are currently no FDA-approved botanicals that follow this Totality of the Evidence guidance for botanical drug development. We will meet these world-class requirements and challenge US development in a foolproof manner.

2-7. Development Requirements for Botanical Medicines (Products) Sought by the US FDA: Drug quality control



GACP, basic structure

GACP: Good Agricultural and Collection Practice



Furthermore, the FDA requires the following:

- ✓ Develop a DNA testing method to confirm original (source) plants **Scientific**
- ✓ Identify specific compounds from among plant species, and quantify as a management indicator **Specific**
- ✓ Select and fix focus on several crude drug production areas that are geographically adjacent
→ Conduct a comprehensive physical chemistry examination of each crude drug lot, acquire crude drug quality in set production areas over a 3-5 year period, and geographically manage over time the quality originating from each production area **Stable supply of uniform crude drugs**

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As an example of the development requirements for botanical drugs, we present the issue of crude drug quality control.

The GACP, which I mentioned earlier, is the good agricultural practices for medicinal plants issued by WHO in 2003. We have established and are operating our own Tsumura crude drug GACP system, and through communication with the FDA, we will resolve the issues shown at the bottom of this slide to further evolve our crude drug GACP system.

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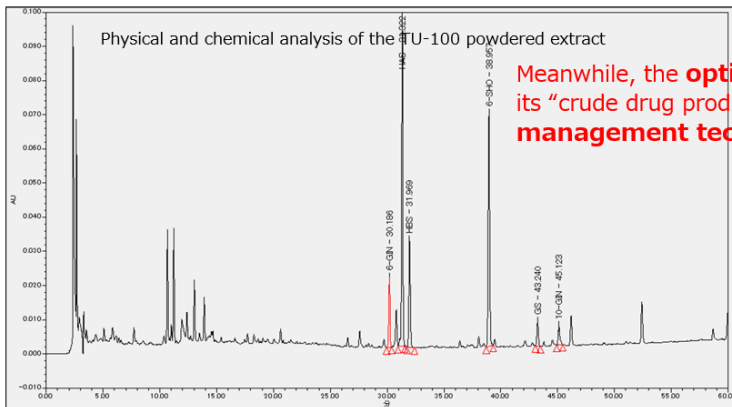
2-8. Development Requirements for Botanical Medicines (Products) Sought by the US FDA: CMC development



Features of botanical medicines: Variations between lots inevitable

- Multi-components (mix of diverse compounds)
- Extremely difficult to identify all substance levels
- Differences between lots, including variety of raw material plants, cultivation areas, harvest years, weather and agricultural methods

CMC: Chemistry, Manufacturing and Control



Meanwhile, the **optimal strength** of Tsumura is its "crude drug production control/lot management technology"

The assessment of the validity of the width in variation is determined by making a comparison with the results of clinical trials and bioassay trials

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Another example of the development requirements of the US FDA is the challenges of CMC development.

Since the raw materials of botanical drugs are natural products, lot-to-lot variations are inevitable. The greatest difficulty in developing botanical drugs as ethical drugs is controlling this lot-to-lot variability.

On the other hand, our greatest strength lies in our crude drug production management, including crude drug cultivation, and lot management technology. We will continue to strive to leverage this strength, backed by the trust and achievements of our company, which has been in business for more than 130 years.

2-9. Obtained Results and Ripple Effect owing to US Development of TU-100 ①



Results	Ripple effect
1. Clinical trial on safety/efficacy	Acquire evidence for TU-100 and deepen understanding of pharmacology
2. Intestinal bacteria research	Accumulate knowhow for intestinal bacteria research
3. Human blood pharmacokinetics	Pioneer of the same trial method for plant extraction formulations. → Enhance package insert
4. Survey on frequency of side-effects	Quantify safety data for Kampo medicine owing to a scale of data consisting of 3,000 cases
5. Build a crude drug reference database	Establish a method for a raw material crude drug lot comparison and management using a principal component analysis
6. Systemize the quality control method in accordance with global standards	Implement PIC/S GMP and GACP in Kampo manufacturing

Expand/apply to other Kampo medicines

Improve the quality of Kampo medicine

PIC/S : Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme.

GMP: Good Manufacturing Practice. Standards related to manufacturing management and quality control

GACP: Good Agricultural and Collection Practices.

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Although the development of the TU-100 in the US has taken a long time due to the above-mentioned difficulties, there are many results that have been achieved through this process. First, the results of safety, efficacy, and clinical trials have contributed to an increase in the number of prescriptions in actual clinical practice through the acquisition of evidence for TU-100 and a deeper understanding of its pharmacodynamics.

In the area of intestinal bacteria research, in response to the FDA's remarks, we have entered into a joint research agreement with a world-class research institute in the US, and have acquired expertise in research on intestinal bacteria.

The difficulty in human blood pharmacokinetic testing is the technology to identify the target of measurement from among the myriad of candidate compounds derived from Kampo medicines, as well as the technology for quantitative analysis of trace components in blood samples.

Before the survey on the frequency of adverse drug reactions, we could only say that the risk of adverse drug reactions was low when explaining the safety of Kampo medicines. After the survey on the frequency of side effects of Daikenchuto, 3,269 patients taking Daikenchuto medication were surveyed, resulting in 64 cases of 72 adverse reactions with an incidence rate of 2%. Thus, for the first time in the Kampo industry, macro safety information can be explained numerically.

These results, obtained in accordance with the FDA's instructions, have now become well-established know-how that has been expanded and applied to other Kampo medicines. Some of the results are also reflected in the attached documents.

Regarding the establishment of a crude drug reference database, the FDA has proposed that data on raw material crude drugs be obtained by region of origin and that this be analyzed in a database. We aim to establish a methodology for lot comparison and quality of raw material crude drugs using principal component analysis, which is a commonly used method for multivariate statistical analysis.

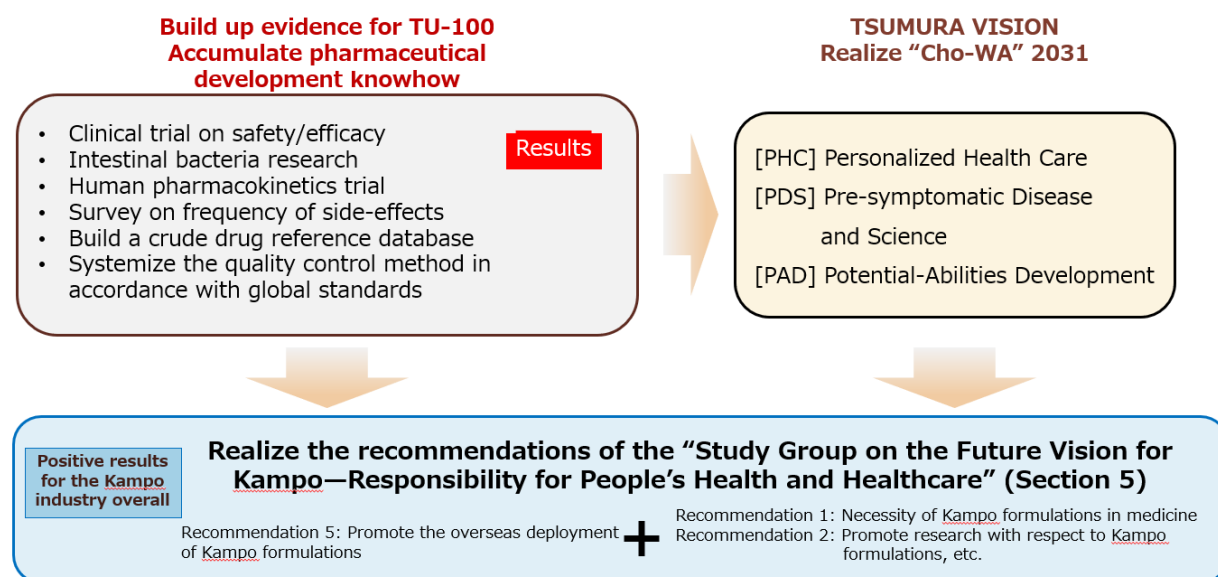
This achievement has contributed greatly to the promotion of PIC/S_GMP and GACP compliance in the manufacture of Kampo medicines. The results of these 5 and 6 have been a major driving force in improving the overall quality of our company's Kampo medicines production.

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PHC : Personalized Health Care, PDS : Pre-symptomatic Disease and Science, PAD : Potential-Abilities Development

Furthermore, the results of TU-100 US development have not only contributed to building evidence for TU-100 and accumulating drug development know-how. It is one of the driving forces to realize our company's TSUMURA VISION "Cho-WA" 2031.

In particular, in relation to PAD or Potential-Abilities Development, the TU-100 US development is a challenge to cultivate a corporate culture that draws out individual potential through dialogue with KOLs and healthcare professionals in Japan and overseas, and to develop a Kampo business that has no model in the world. It is truly creating opportunities for the development of global human resources.

Please see the bottom of this slide. The realization of the Study Group on the Future Vision for Kampo—Responsibility for People’s Health and Healthcare has had a positive effect on the Kampo industry as a whole. Many stakeholders outside of the Company are paying close attention to the future of the TU-100 US development and have high expectations for the initiative.

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- Analysis of TU-100 clinical trial data (summer)
- Address FDA inquiries on the CMC^{※1} development strategy
- Propose alliance activity policy



Reset the master schedule for TU-100 US development
Development activities for Phase III trial^{※2}

※1 CMC: Chemistry, Manufacturing and Control

※2 Assuming success of late stage PII clinical trial

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This is the outlook for the future.

First, let me explain our short-term plan. The results of the TU-100 clinical trial are currently undergoing data cleaning. In deciding on the re-scheduling of the TU-100 US development master schedule and development activities for the PIII trial, we will announce our development policy to the public at an appropriate time after repeated surveys of the medical market and comprehensive discussions on the feasibility of CMC development strategies, alliance activity policies, and other issues.

That is all. Since the results of the clinical trial are not yet known, we reported the completion of patient enrollment in the late phase II trial as an interim analysis, and presented a summary of our efforts to date. Please accept my apologies for omitting the details of the long-term outlook. Thank you for your attention.

Kitamura: Thank you very much. This concludes the explanation.

Question & Answer

Kitamura [M]: Okay, we will now have time for questions and answers.

First, we will take questions from those in attendance at the venue and then from web participants. Please note that each person is limited to two questions at a time. Please note that the content and audio of the questions will be posted on our website at a later date, along with the presentation materials.

We will now take questions from the audience. Please raise your hand and we will call you. UBS Securities, Mr. Sakai.

Sakai [Q]: My name is Sakai from UBS. First of all, I would like to ask the President. I think that in a sense, the 20% increase accompanying the NHI drug price revision can be taken as a sign that the government understands the usefulness of the Kampo medicines that Tsumura has been working on. On the other hand, the forecast for this fiscal year is based on the assumption that volume growth will probably be only about 2%.

Therefore, as I often write in my reports, expanding the base of demand for Kampo medicines will continue to be an issue from now on. You mentioned that the rules of the game have changed and that your company's business environment has changed, and based on this, you will probably issue a medium-term management plan in the future. In light of the changes in your initiatives and the recent NHI drug price revision, what are your thoughts on whether or not any new winds will blow, or whether or not you will be able to make them blow, and what are your thoughts in this area?

Kato [A]: Thank you. We recognize that the business environment has changed significantly since NHI prices changed this way. On the other hand, there are still some issues to be addressed. Although limited shipments have decreased, they are still continuing to some extent, and we must first ensure a stable supply and strengthen our system to achieve this.

Of course, limited shipments are being made in response to greater-than-expected demand, but in this sense, we are fundamentally strengthening our system in response to the fact that demand is firming up.

We expect demand in the domestic Kampo market to continue to grow. As I have explained earlier, there are many urgent issues that remain in our country, and there are many roles that only our drugs can play in these areas, in other words, the roles that multi-component, pharmaceuticals derived from natural ingredients can play. Especially for the elderly, who have multiple diseases, we believe that the characteristics of drugs with multiple components should be utilized.

As shown in the previous slide, one of our consistent business strategies is to expand the market for prescription Kampo products, which will naturally allow us to build up a variety of evidence and collect information on the mechanisms of action and side effects. Naturally, we also need to develop areas where we can respond to new diseases with prescription Kampo products.

Therefore, we have always aimed to reach a point where one out of every two physicians is a physician who prescribes more than 10 prescriptions, or more than 50%, and this will continue.

I have to be a little careful in how I phrase this, but I call it a research exploratory pipeline, cases where Kampo medicines can be used within the scope of existing indications for new diseases. For example, in the past, Yokukansan was used for the peripheral symptoms of dementia, especially for the agitation system. Originally,

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the market for this drug was only several hundred million yen, but as a result of basic clinical research, it has become widely used.

As you saw in the graph earlier, the use of Goreisan for edema in patients with heart failure is increasing, and we are currently conducting research to create an environment where Goreisan can be used based on solid evidence.

In addition, the number of patients with frailty is expected to increase in the future. It is important for patients to be able to take care of themselves for a long time before they become frail. Therefore, we are developing a new market for drugs that contribute to extending healthy life expectancy, such as Ninjin'yoeito and Kamikihito, by firmly supporting such a role on an R&D basis.

We recognize that our company is required to develop and drive new demand for Kampo in both of these areas. We would like to take advantage of the upturn in the business environment to allocate resources in order to create a new market, and to play a role in providing evidence-based treatment to a large number of patients. That is all.

Sakai [Q]: Thank you very much. And one more thing about the China business. I was curious about the President's comments regarding the expansion of sales channels for crude drugs. I assume that this is a term that ended, but will you be shifting your strategy to expanding sales channels for drug pieces? I think you have said up until now that the Chinese business must first be considered with a focus on M&A.

I don't know whether to say that the acquisition of Unisplendour was a failure or not, but I got the impression that it was a lesson learned and that it would be more efficient and successful if the Company expands on its own instead of through M&A.

Do you still intend to expand both through M&A and by your own company, or have you come to the conclusion that M&A in China will be difficult, even for your company?

Kato [A]: Thank you. We have consistently communicated that there has been no change in our strategic policy, and there has been no change at all this time. Originally, we have been working on a separate platform for our business. So the essential idea is that we are doing it concurrently.

Therefore, what I have just shown you is a crude drug platform. The crude drug platform is a business that is based on the raw material of crude drugs and is exploring what value can be added to the business to contribute to the health of the people of China. Naturally, we have done this early on and will continue to do so on a constant scale.

For example, drug pieces, which are not well developed in Japan, are a method of prescribing chopped crude drugs in a customized formulation for each patient. This alone is a market of about JPY4 trillion in China.

Unfortunately, in Japan, most of the products are standardized extract drugs like ours, so this type of business has not developed domestically, but on the flip side, both are necessary. If we treat a large number of people with a standard treatment, we will be able to obtain a variety of evidence and evaluate the effectiveness of such treatment.

On the other hand, each person's disease state is different and there are individual differences, so in that sense, providing prescriptions tailored to each person's needs is also highly needed and effective.

This is not possible in Japan, but it is possible in China. I am sorry to say that we have not been able to make much headway in the drug pieces business and the extract business. The traditional Chinese medicinal products business, which I mentioned as the most important issue for this fiscal year, is our strongest area of

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expertise, so there is no way that we will shrink this business at all, and our policy remains the same of making it our core business.

However, the environment of business is quite tough in some areas, and the case of Shaanxi Unisplendour mentioned earlier is not a failure. Unfortunately, the project was not completed due to unforeseen circumstances in a successful situation. We have not changed our policy at all, nor have we changed our way of thinking at all, as we are naturally negotiating with new partners and so on. That is all.

Sakai [Q]: Sorry, just one thing. Yes or no is fine, but can I assume that your relationship with Ping An will remain the same?

Kato [A]: It hasn't changed at all.

Sakai [M]: Thank you very much.

Kitamura [M]: Thank you very much. Now, Mr. Akahane from Tokai Tokyo Intelligence Laboratory.

Akahane [Q]: I am Akahane from Tokai Tokyo Intelligence Laboratory. I would love to hear about the TU-100 in the US, but since I can only ask two questions, I will limit myself to questions about business results.

First of all, although the actual results were favorable, 4Q sales were JPY35 billion with an operating profit of JPY880 million. There are limited shipments and the larger mainstay areas increase by 50% NHI. Of course, if you're a medical institution, you want, as temporary demand.

Looking at these numbers alone, I can see that you didn't respond to them, but in fact, the medical institutions must have told you to bring them if it goes up this much, . How did your company respond to this? Also, I was wondering if you could tell me how this relates to limited shipments. It doesn't have to be quantitative. It would be helpful if you could just give us an idea of what it looked like. This is the first question.

Sorada [A]: I am Sorada, Head of the Sales and Marketing Division. Thank you for your question. As you mentioned, there was a strong demand from various medical institutions to make purchases. However, if products are unevenly distributed or missing in some areas, it would cause inconvenience to patients. Therefore, we asked for the cooperation of our distributors and shipped about the same amount as the previous year. We kept our shipments about 5% higher than the previous year.

Many of the comments we have received indicate that TSUMURA's efforts over the years have paid off.

Akahane [Q]: I understand it very well. I would like to hear about the forecast, but earlier than that, the drug price went up significantly 21.6% weighted average , so of course this is a stable supply for the administration. I had a tour of the factory the other day, and there is only about a two-week supply of stock in Japan. I believe that since they raised prices, they consider this to be a stable long-term supply. I will ask you about the details of this JPY68 billion investment in due course, but for now, what do you envision for the long-term investment? Shanghai and Tianjin would not be risk averse at all from a China risk perspective. You don't have to give me numbers, but do you have any medium- or long-term indicators at this point regarding warehouses, production lines, or inventories?

Handa [A]: Thank you for your question. I will now answer your question. It may be somewhat closer to an image, though.

You told me that you had visited the plant and now commented on the inventory. I mentioned earlier that we will also build a warehouse. We are planning to secure a stockpile of these raw material crude drugs for the current fiscal year and beyond.

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As for facilities related to manufacturing after this fiscal year, we have been working on Tianjin for a long time, and although the first phase finally started operating last year, the second and third phases are still to come. As planned, this will be largely completed this fiscal year, but we will make investments for the second and third fiscal years this year and next. This is, first of all, the scope of what we have explained so far.

I also mentioned that future plans will be decided in the medium-term management plan. However, as you have pointed out, our production facilities are not solely focused on China. We still have room for expansion at the Ibaraki Plant and other facilities, and we are planning to increase facilities not only for the upstream process but also for the downstream process, or the granulation packaging process. I mentioned earlier that this will take place over a period of several years. I have an image that this will include the upstream process in Japan and further reinforcement of the downstream process.

In this sense, as you pointed out, we will hold inventories in stock, expand warehouses, and continue to expand production facilities in China, as well as in China and in Japan, in the upstream and downstream processes. The figures I just mentioned are such an image. That is all.

Akahane [Q]: I understand very well. And just to confirm, you have 90% of your crude drugs procured from China. Will you announce in the medium-term plan how you will increase the procurement ratio from sources other than China?

Kato [A]: The ratio doesn't change easily. We will certainly increase the amount of crude drugs in Japan, but we need 119 crude drugs to make 129 prescriptions. However, since they are plants, some plants are difficult to cultivate in Japan. In this sense, we will certainly expand the cultivation of crude drugs in Japan, and the amount will increase, but Procurement ratio from China is not likely to decline.

Therefore, our basic concept is to have as much as possible of what can be grown in Japan, or in Laos or Vietnam if it is of southern origin, so that we can diversify as much as possible, but there is a limit. That is all.

Akahane [M]: I understand very well. I will ask additional questions if there is enough time.

Kato [M]: Thank you. Mr. Sugii will answer about the concept of production.

Sugii [A]: Excuse me. I would like to add a few words regarding the expansion of production facilities. As Mr. Handa explained earlier, Tianjin is currently undergoing the first, second, and third phases of construction, and the first phase has just started operating, and the second and third phases are about to start up. At the timing of the start of the third phase, the ratio of production volume between Japan and China will be roughly half, or about 50:50.

However, this will only be temporary, and after that, as I mentioned earlier, we are planning to expand to domestic factory sites in Ibaraki and other locations to bring the manufacturing balance to about six to four, or six in Japan and four in China, in the future. We will consider what to do in the future, but for the time being, our plan is to increase the ratio to that level. That is all.

Kitamura [M]: Thank you very much. Now, Mr. Kawamura, SBI SECURITIES.

Kawamura [Q]: Thank you for your explanation. This is Kawamura of SBI SECURITIES. First, can you be more detailed about the earnings forecast?

The NHI drug price revision raises the unit price by roughly 22%, the top line by 1% to 2% due to volume effects, and the NHI drug price revision adds JPY27 billion to operating profit. Based on my manual calculations, the plan appears to be conservative. Can I ask more about your assumptions, such as that there are limited

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shipments, that there are some more unseen impact included, or that it is simply conservative or not conservative?

Handa [A]: Thank you for your question. First of all, let me conclude that we do not intend to be extremely conservative. In that sense, as I indicated in the operating profit section, as for sales, there will be some impact of the limited shipments until H1 of this year, but the production that is slightly restricted now due to the renovation work in Shanghai will be resumed this summer.

The Tianjin factory, which began full-scale operations around the beginning of last year, will also be in full swing this year. In this sense, manufacturing will gradually increase. With this as the core, we expect sales in Japan to return to a growth trajectory this fiscal year, and in China, we fully expect top-line growth as planned.

As for the JPY27 billion in NHI prices that you pointed out, this is also something that can be calculated. As for the question of whether the Company is conservative, I think there may be various negative factors. The purpose of the NHI drug price revision this time is to strengthen the stable supply and global quality of our products, and of course, we do not intend to make any unnecessary investments. These are included on the right hand side, investments including stable supply.

Other raw material crude drugs, raw materials, and foreign exchange rates are current figures, so there is nothing particularly conservative about them.

I mentioned the expansion of cultivation and automation as typical examples of cost reduction. By continuing to implement these measures, we will offset the negative impact and keep it at this level.

We assume that these self-help efforts must be done quickly. That's all from me.

Kawamura [Q]: I understand. Thank you very much. I know it's a little early, but could you give me a hint about the next term?

I think it is positive that NHI drug prices have risen so much this time, but I am still very concerned about what will happen to these prices next fiscal year and what the unit price will be. Up until now, a few years ago, yes, NHI prices were lowered by 2% to 3%. Then you grew in volume, and now are you going back to a figure like 2 to 3% increase in domestic sales in total? Or do you have a policy, background, or institutional story that would allow for more discontinuous growth, or just a hint in this area?

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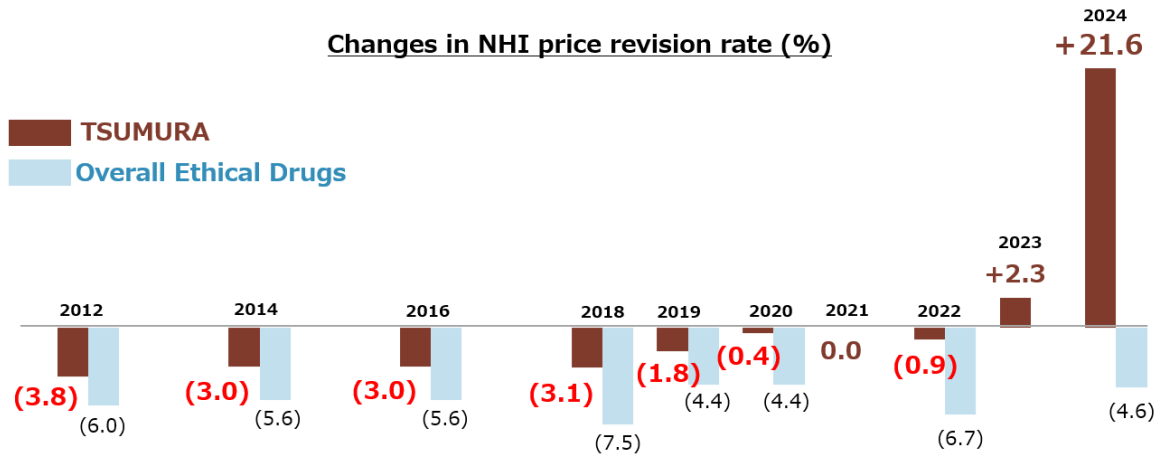
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Domestic Business: NHI Price Revision Ratio



In the NHI price revision in FY2024, 66 prescriptions will be subject to recalculation of unprofitable products, with a weighted average increase of +21.6%.



Revision rates for 2021 and 2023 are not disclosed because they are mid-year revisions.

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Kato [A]: Thank you. Changes in drug prices can be found on page 58. The reductions are becoming much smaller for Kampo. A positive revision of 21%, but a negative one of 0.9%. Compressed to 0.9%.

The Head of Sales and Marketing Division has said that he will conduct sales activities in such a way that NHI drug prices will not be lowered in the future. So, the basic idea is to conduct business activities that do not lower the NHI price and do not lower the amount raised by the price re-evaluation.

The system itself is not something that we can foresee. We do not anticipate any drastic changes in the system, as the entire industry has opposed any policy that would cause a loss of predictability in management.

Therefore, while we do not expect to see price re-evaluation as money-losing products one after another, our basic approach is to maintain the portion of the increase this time and to boost the overall volume by increasing the quantity. That is all.

Kawamura [Q]: Thank you very much. Does this mean that we can basically expect that the sales will be made in such a way that there will be no decline in the range of 3% or 4% in the future?

Kato [A]: It means selling it so that it doesn't go down 3%. The idea is to sell the product so that it will not go down if possible.

Kawamura [M]: Thank you very much.

Kitamura [M]: Thank you very much. We will now close the floor for questions from the audience and take questions from web participants.

Participants at the venue can also ask additional questions if they have any. Mr. Akahane, please go ahead.

Akahane [Q]: Sorry, this is the second time. Frankly speaking, I was surprised to see the financial results this time. Because, of course, since the NHI price went up 21.6%, that would be a 20% increase in sales and double the profit, since the OP margin is 13.3% to begin with, so the profit margin would double given that demand would not drop.

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However, at first, I was not expecting that you would give such a strong figure. As is the case with many basic pharmaceutical companies in Japan, they tend to issue earnings forecasts with the eyes of the government more in mind than those of their shareholders. It is good about the Ministry of Finance that since there is an NHI drug price revision every year, you are already profitable and you will increase your dividend significantly. Your company's stock price is up today, so your net asset value per share is JPY3,570, and you were able to avoid price-to-book value ratio below 1, which is great.

From the Ministry of Health, Labor and Welfare's point of view, if a company is making a profit by raising prices, why should they complain about increasing dividends? I think that ordinary pharmaceutical companies are conscious of the eyes of the government, and as a result, they come up with figures like these. With the NHI drug price revision for the next fiscal year, I think it will be difficult to say that you are making a profit, but what was your intention in putting out these figures at the beginning of the fiscal year?

Kato [A]: Thank you. There is no intention. We have discussed the same thing at the Board of Directors meetings. Naturally, we have thoroughly discussed what we need to do in light of the situation regarding NHI prices.

The important thing is definitely the stable supply first. At the same time, we believe that, although Kampo products are pharmaceuticals derived from natural ingredients, there is no drug in the world of this level of quality, sold in such large quantities, and used under the insurance medical care system.

Therefore, we have to be a manufacturer of pharmaceuticals derived from natural ingredients that meet global standards.

In addition, it is already clear that the background of the widespread use of Kampo products up to this point is undoubtedly the result of research. The "drug fostering" program formulations and "growing" formulations that we have developed so far have enabled us to build evidence, clarify the mechanism of action, and accumulate basic and clinical research to respond to newer diseases, even within the scope of indications, and have made it possible to use these drugs for patients and diseases for which they have not been available until now.

We are allocating money to the public as a return of profits from the NHI price revision.

At the same time, there is still the TSE's prime market listing criteria. Currently, our PBR does not reach 1.4x, the average for primes. However, since we are a publicly traded company, we must satisfy both perspectives. There is no doubt that it was a very difficult decision to make.

I hope you will understand that these calculations were made as a result of thorough discussions at the Board of Directors meetings. That is all.

Akahane [Q]: I understand very well. Thank you very much. Finally, I have a question related to development in the US.

I have been looking at your company for quite some time. The FDA in the US has very negative things to say about Kampo medicines. In Europe, there are herbal medicines, so I guess there is a certain level of understanding. It is true that there is a problem of variability in phytopharmaceuticals, but your company, no, it is not, and that is one of its great strengths. It is quite a challenge when you consider cost-effectiveness.

However, from the outside, Chinese people are very fussy about evidence, even more so than the Japanese, so I think that proving in the US would be a great advantage for the China business that your company is currently focusing on. If you don't intend to make much money in the US, I think it would be cost-effective, but is this wrong? Is it a skeptical view?

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Kato [A]: No, you are not wrong. Basically, we would like to use the product primarily for the benefit of patients in the United States. If the US approves, there will naturally be opportunities in China, Southeast Asia, and other markets as well.

Of course, we are not just trying to make the US market profitable in terms of investment cost-effectiveness, and as was explained earlier, there are definitely positive factors for Japan.

We are continuing this because we believe it is worth doing in total, and although the hurdles are very high, we are taking on this challenge based on the idea that it is not out of our reach. I would appreciate your understanding.

Akahane [M]: I understand very well. Thank you very much.

Kitamura [M]: Any other questions?

Sakai [Q]: Excuse me. UBS, Sakai. I also have a question about TU-100. Have you seen the results of Phase IIa? I think the report is that the patient enrollment for Phase IIb has been completed, and if that is successful, you will move on to Phase III. The protocol for Phase III has not yet been determined. Until Phase IIa, I think it was a physician-led clinical trial led by the Mayo Clinic and others, but will that scheme change as well?

In other words, will your company be the sole developer? Mr. Kaneko, can you tell us what the probability of success for Phase IIa is?

Kaneko [A]: Thank you for your question. In the US, there was a first trial and a second trial, and after seeing the effects of the first trial, we are now entering the second trial. We are doing this trial because of the good results of the first trial.

We have received very unique data on the effects of POI, for example, a decrease in the incidence of complications, and also a decrease in the index of nausea and vomiting, and if there is a significant difference, a shorter hospital stay. We have received comments from third-party doctors that this is worth developing.

We also had the FDA review this data and comment that this is worth doing as a Proof of Concept trial just prior to PIII, and we are conducting this trial.

The results are still to be seen, but the results of the first trial were good, so we are confident that we will be able to challenge the Phase III trial if we get good results this time.

Sakai [Q]: Is it correct in my understanding that Phase III will be scaled according to the usual protocol, for example, with a placebo?

Kaneko [A]: For Phase III, it is definitely a validation trial, so I think a large-scale trial is required for the number of N as well as placebo. However, since this is a TBT trial, we have used placebo in this trial and in the previous trial to make comparisons.

Sakai [M]: I understand. Thank you very much.

Kitamura [M]: We have time to take at least one other question. Anybody? Now that we have almost reached the end time, we will now conclude the briefing for business results for FY2023.

Thank you for joining us today.

[END]

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