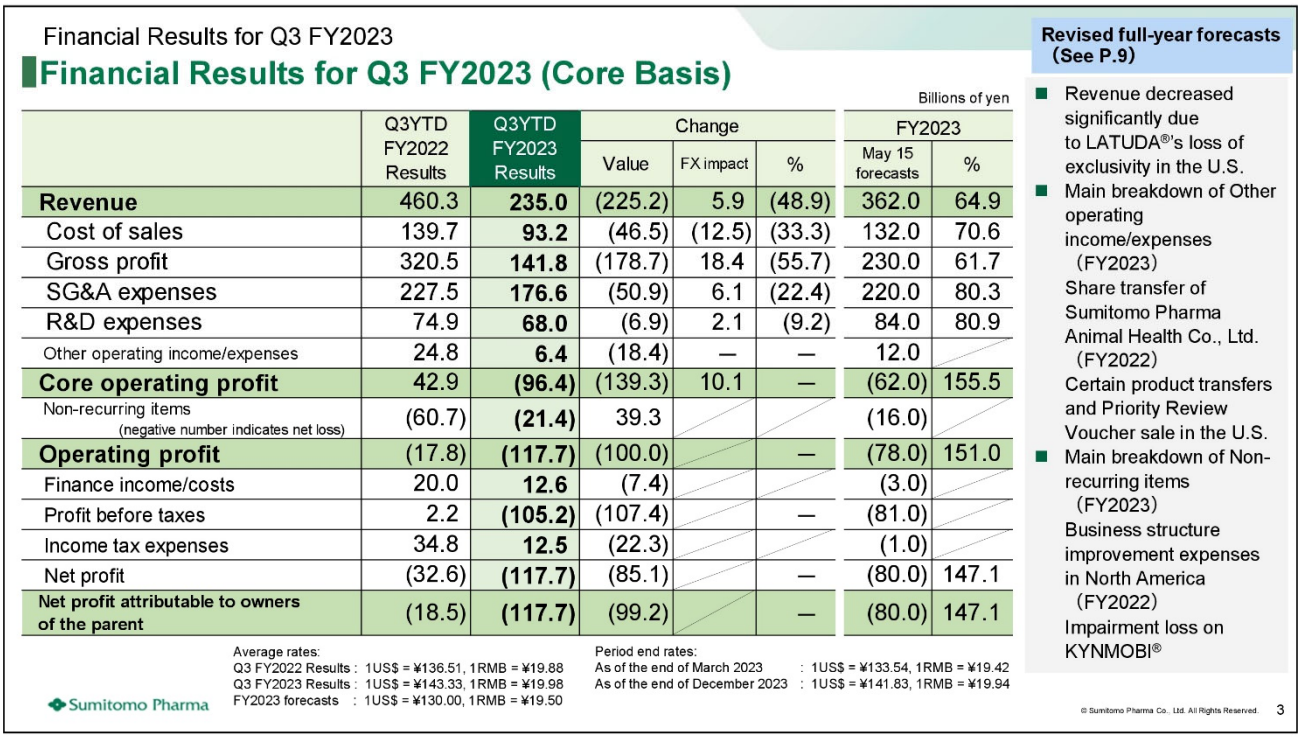
Q3 Financial Results Briefing for FY2023

[Date]	January 31, 2024	
[Time]	18:00 – 19:18	
	(Total: 78 minutes, Presentation: 19 minutes, Q&A: 59 minutes)	
[Venue]	Webcast	
[Number of Speakers]	5	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Senior Managing Executive Officer
	Yoshiharu Ikeda	Member, Board of Directors, Managing Executive Officer
	Naoki Noguchi	Executive Officer, Vice President, Head of Corporate Communications
	Koji Ishida	Vice President, Head of Global Finance

Presentation

Noguchi: As the time has come, we would like to begin the Sumitomo Pharma Q3 financial results briefing for FY2023. Now, Mr. Ishida, please go ahead.



Financial Results for Q3 FY2023

Financial Results for Q3 FY2023 (Core Basis)

Billions of yen

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change			FY2023	
			Value	FX impact	%	May 15 forecasts	%
Revenue	460.3	**235.0**	(225.2)	5.9	(48.9)	362.0	64.9
Cost of sales	139.7	**93.2**	(46.5)	(12.5)	(33.3)	132.0	70.6
Gross profit	320.5	**141.8**	(178.7)	18.4	(55.7)	230.0	61.7
SG&A expenses	227.5	**176.6**	(50.9)	6.1	(22.4)	220.0	80.3
R&D expenses	74.9	**68.0**	(6.9)	2.1	(9.2)	84.0	80.9
Other operating income/expenses	24.8	**6.4**	(18.4)	—	—	12.0	
Core operating profit	42.9	**(96.4)**	(139.3)	10.1	—	(62.0)	155.5
Non-recurring items (negative number indicates net loss)	(60.7)	**(21.4)**	39.3			(16.0)	
Operating profit	(17.8)	**(117.7)**	(100.0)		—	(78.0)	151.0
Finance income/costs	20.0	**12.6**	(7.4)			(3.0)	
Profit before taxes	2.2	**(105.2)**	(107.4)		—	(81.0)	
Income tax expenses	34.8	**12.5**	(22.3)			(1.0)	
Net profit	(32.6)	**(117.7)**	(85.1)		—	(80.0)	147.1
Net profit attributable to owners of the parent	(18.5)	**(117.7)**	(99.2)		—	(80.0)	147.1

Average rates:
Q3 FY2022 Results : 1US$ = ¥136.51, 1RMB = ¥19.88
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of December 2023 : 1US$ = ¥141.83, 1RMB = ¥19.94

Revised full-year forecasts (See P.9)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Main breakdown of Other operating income/expenses
  (FY2023)
  Share transfer of Sumitomo Pharma Animal Health Co., Ltd.
  (FY2022)
  Certain product transfers and Priority Review Voucher sale in the U.S.
- Main breakdown of Non-recurring items
  (FY2023)
  Business structure improvement expenses in North America
  (FY2022)
  Impairment loss on KYNMOBI®

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Ishida: I am Ishida, Vice President, the Head of Global Finance. Based on the presentation materials, I will now report on our performance for Q3 of FY2023.

Please refer to page three. I will report on the Q3 financial results. These figures are presented on a core basis in accordance with IFRS.

Revenue was JPY235 billion, a decrease by JPY225.2 billion in the same period last year. There was a decline in revenue across all segments, including Japan, North America, and Asia.

Despite the decrease in SG&A expenses, and the recording of other operating income due to the transfer of shares in Sumitomo Pharma Animal Health Co., Ltd., the impact of the decline in gross profit due to reduced revenue was significant. As a result, core operating profit decreased by JPY139.3 billion YoY, resulting in a core operating loss of JPY96.4 billion.

As a non-recurring item, we recorded JPY20.5 billion in retirement benefits associated with the restructuring of our North American group companies. Consequently, operating profit decreased by JPY100 billion from the same period last year, resulting in an operating loss of JPY117.7 billion.

Profit before taxes for the quarter recorded a foreign exchange gain of JPY12.4 billion due to the weaker yen at the end of the quarter. However, the substantial reduction in operating profit led to a decrease of JPY107.4 billion YoY, resulting in a profit before taxes quarterly loss of JPY105.2 billion. As a result, net profit attributable to owners of the parent also significantly decreased, resulting in a loss of JPY117.7 billion.

In light of recent trends, we have revised our full-year financial forecasts. I will explain the details later on.

Financial Results for Q3 FY2023

Financial Results for Q3 FY2023 (Core Basis) - vs. Q3 YTD FY2023 Plans

Billions of yen

	Q3YTD FY2023 Plans	Q3YTD FY2023 Results	Change			
			Value	%	FX impact	% (w/o FX)
Revenue	261.3	**235.0**	(26.3)	89.9	11.9	85.4
Cost of sales	95.4	**93.2**	(2.2)	97.7	5.2	92.3
Gross profit	165.9	**141.8**	(24.1)	85.5	6.7	81.5
SG&A expenses	167.6	**176.6**	9.0	105.4	12.1	98.2
R&D expenses	63.1	**68.0**	4.9	107.7	4.0	101.3
Other operating income/expenses	7.0	**6.4**	(0.6)		—	
Core operating profit	(57.8)	**(96.4)**	(38.6)	—	(9.4)	—

Average rates:
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
FY2023 Plans : 1US$ = ¥130.00, 1RMB = ¥19.50

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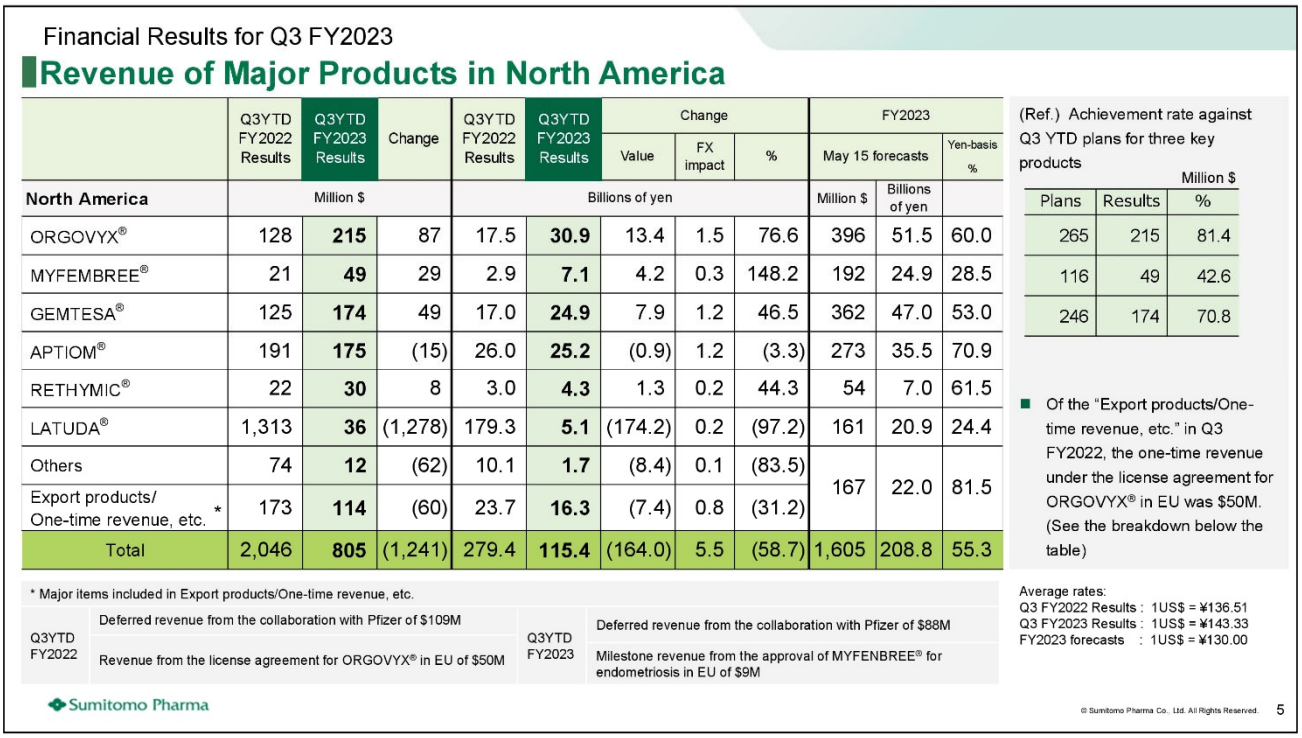
Page four presents a comparison of the Q3 financial results on a core basis against our internal budget.

Revenue was JPY235 billion, achieving 89.9% of the plan. The real achievement rate, excluding FX rates differences, was 85.4%. The performance in Japan and Asia was broadly in line with the plan, but North America fell short of expectations.

SG&A expenses amounted to JPY176.6 billion, reaching 105.4% of the plan. The real achievement rate, excluding FX rates differences, was 98.2%.

R&D expenses were JPY68 billion, reaching 107.7% of the plan. The real achievement rate, excluding FX rates differences, was 101.3%. Thus, both SG&A expenses as well as R&D expenses were broadly in line with the plan on a real basis, excluding FX rates effects. Other operating income and expenses amounted to JPY6.4 billion.

As a result, the core operating line recorded a core operating loss of JPY96.4 billion.



Financial Results for Q3 FY2023

Revenue of Major Products in North America

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change			FY2023		
						Value	FX impact	%	May 15 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billions of yen	
ORGOVYX®	128	**215**	87	17.5	**30.9**	13.4	1.5	76.6	396	51.5	60.0
MYFEMBREE®	21	**49**	29	2.9	**7.1**	4.2	0.3	148.2	192	24.9	28.5
GEMTESA®	125	**174**	49	17.0	**24.9**	7.9	1.2	46.5	362	47.0	53.0
APTIOM®	191	**175**	(15)	26.0	**25.2**	(0.9)	1.2	(3.3)	273	35.5	70.9
RETHYMIC®	22	**30**	8	3.0	**4.3**	1.3	0.2	44.3	54	7.0	61.5
LATUDA®	1,313	**36**	(1,278)	179.3	**5.1**	(174.2)	0.2	(97.2)	161	20.9	24.4
Others	74	**12**	(62)	10.1	**1.7**	(8.4)	0.1	(83.5)	167	22.0	81.5
Export products/ One-time revenue, etc. *	173	**114**	(60)	23.7	**16.3**	(7.4)	0.8	(31.2)			
Total	2,046	**805**	(1,241)	279.4	**115.4**	(164.0)	5.5	(58.7)	1,605	208.8	55.3

(Ref.) Achievement rate against Q3 YTD plans for three key products

Million $

Plans	Results	%
265	215	81.4
116	49	42.6
246	174	70.8

- Of the "Export products/One-time revenue, etc." in Q3 FY2022, the one-time revenue under the license agreement for ORGOVYX® in EU was $50M. (See the breakdown below the table)

* Major items included in Export products/One-time revenue, etc.

Q3YTD FY2022	Deferred revenue from the collaboration with Pfizer of $109M	Q3YTD FY2023	Deferred revenue from the collaboration with Pfizer of $88M
	Revenue from the license agreement for ORGOVYX® in EU of $50M		Milestone revenue from the approval of MYFENBREE® for endometriosis in EU of $9M

Average rates:
Q3 FY2022 Results : 1US$ = ¥136.51
Q3 FY2023 Results : 1US$ = ¥143.33
FY2023 forecasts : 1US$ = ¥130.00

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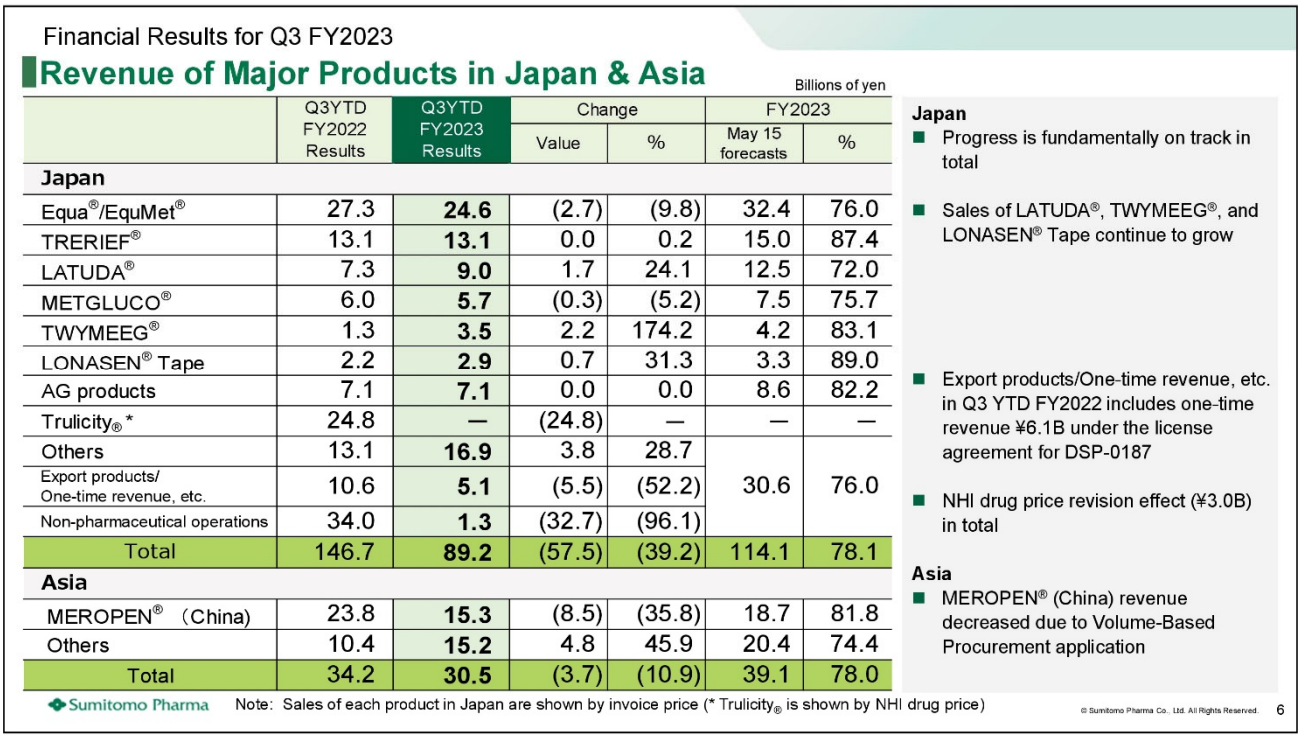
Page five covers the revenue performance of the North America segment.

In the North America segment, although revenue of the Three Key Products, ORGOVYX®, MYFEMBREE®, and GEMTESA®, increased, the end of the exclusive sales period of LATUDA® in the U.S. had a significant impact. As a result, revenue was JPY115.4 billion, a decrease of JPY164 billion compared to the same period last year.

The achievement rate for the Q3 plan for these Three Key Products is provided, but all fell short of their plans.

The slide's lower part details the major items of one-time and milestone revenue.



Financial Results for Q3 FY2023

Revenue of Major Products in Japan & Asia

Billions of yen

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change		FY2023	
			Value	%	May 15 forecasts	%
Japan						
Equa®/EquMet®	27.3	**24.6**	(2.7)	(9.8)	32.4	76.0
TRERIEF®	13.1	**13.1**	0.0	0.2	15.0	87.4
LATUDA®	7.3	**9.0**	1.7	24.1	12.5	72.0
METGLUCO®	6.0	**5.7**	(0.3)	(5.2)	7.5	75.7
TWYMEEG®	1.3	**3.5**	2.2	174.2	4.2	83.1
LONASEN® Tape	2.2	**2.9**	0.7	31.3	3.3	89.0
AG products	7.1	**7.1**	0.0	0.0	8.6	82.2
Trulicity® *	24.8	—	(24.8)	—	—	—
Others	13.1	**16.9**	3.8	28.7		
Export products/ One-time revenue, etc.	10.6	**5.1**	(5.5)	(52.2)	30.6	76.0
Non-pharmaceutical operations	34.0	**1.3**	(32.7)	(96.1)		
Total	146.7	**89.2**	(57.5)	(39.2)	114.1	78.1
Asia						
MEROPEN® (China)	23.8	**15.3**	(8.5)	(35.8)	18.7	81.8
Others	10.4	**15.2**	4.8	45.9	20.4	74.4
Total	34.2	**30.5**	(3.7)	(10.9)	39.1	78.0

Japan

- Progress is fundamentally on track in total
- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Export products/One-time revenue, etc. in Q3 YTD FY2022 includes one-time revenue ¥6.1B under the license agreement for DSP-0187
- NHI drug price revision effect (¥3.0B) in total

Asia

- MEROPEN® (China) revenue decreased due to Volume-Based Procurement application

Sumitomo Pharma Note: Sales of each product in Japan are shown by invoice price (* Trulicity® is shown by NHI drug price)

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Page six discusses the revenue performance of the Japan and Asia segments.

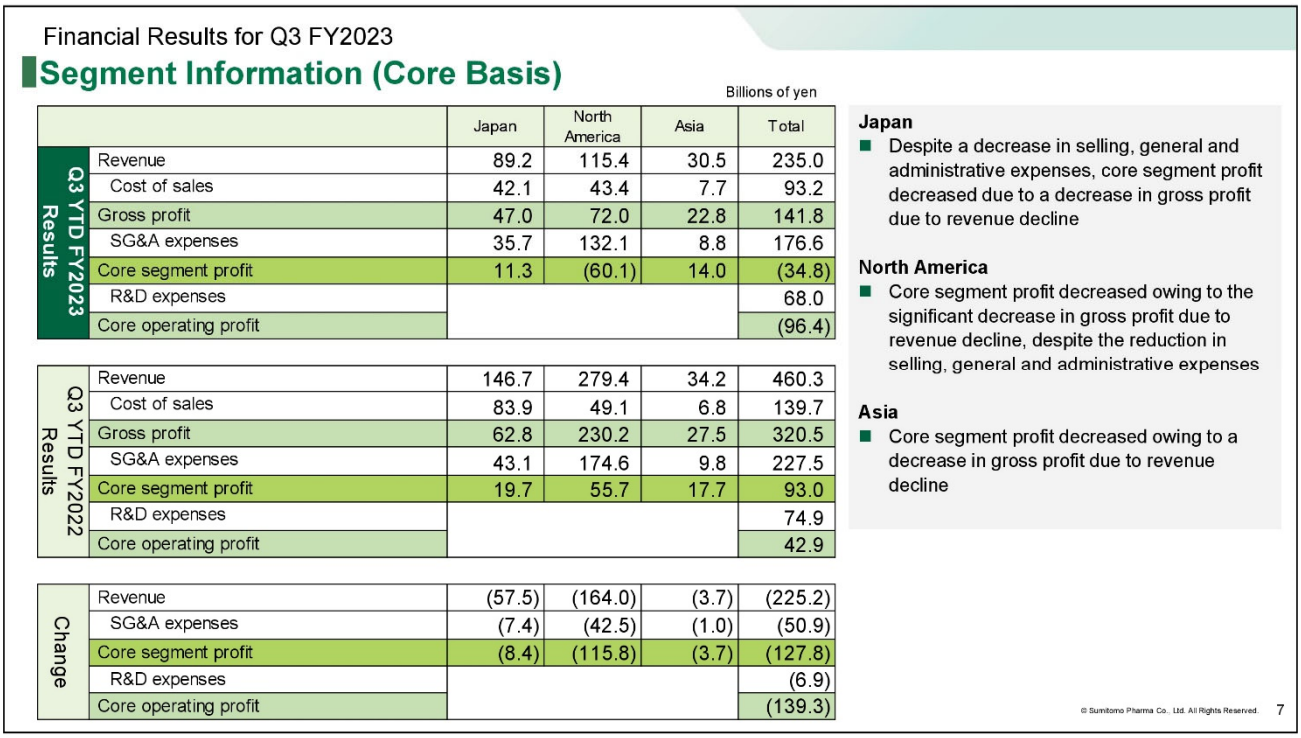
The Japan segment saw a decrease in revenue compared to the same period last year by JPY57.5 billion, amounting to JPY89.2 billion.

While sales of LATUDA®, TWYMEEG®, and LONASEN® Tape increased, the segment overall experienced a decrease in revenue due to factors such as the transfer of subsidiary shares in related businesses, the conclusion of the Trulicity® sales collaboration in December 2022, and a one-time revenue of JPY6.1 billion from the out-licensing of DSP-0187 in the same period last year.

The progress rate against the full-year forecasts is 78.1%, with the segment as a whole progressing almost as forecasted.

The Asia segment experienced a significant decrease in revenue due to the impact of MEROPEN® in China becoming subject to Volume-Based Procurement from November 2022, resulting in a YoY decrease of JPY3.7 billion for the segment.

The progress rate against the full-year forecasts is 78.0%, progressing almost as expected.



Financial Results for Q3 FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
Q3 YTD FY2023 Results	Revenue	89.2	115.4	30.5	235.0
	Cost of sales	42.1	43.4	7.7	93.2
	Gross profit	47.0	72.0	22.8	141.8
	SG&A expenses	35.7	132.1	8.8	176.6
	Core segment profit	11.3	(60.1)	14.0	(34.8)
	R&D expenses				68.0
	Core operating profit				(96.4)
Q3 YTD FY2022 Results	Revenue	146.7	279.4	34.2	460.3
	Cost of sales	83.9	49.1	6.8	139.7
	Gross profit	62.8	230.2	27.5	320.5
	SG&A expenses	43.1	174.6	9.8	227.5
	Core segment profit	19.7	55.7	17.7	93.0
	R&D expenses				74.9
	Core operating profit				42.9
Change	Revenue	(57.5)	(164.0)	(3.7)	(225.2)
	SG&A expenses	(7.4)	(42.5)	(1.0)	(50.9)
	Core segment profit	(8.4)	(115.8)	(3.7)	(127.8)
	R&D expenses				(6.9)
	Core operating profit				(139.3)

Japan
- Despite a decrease in selling, general and administrative expenses, core segment profit decreased due to a decrease in gross profit due to revenue decline

North America
- Core segment profit decreased owing to the significant decrease in gross profit due to revenue decline, despite the reduction in selling, general and administrative expenses

Asia
- Core segment profit decreased owing to a decrease in gross profit due to revenue decline

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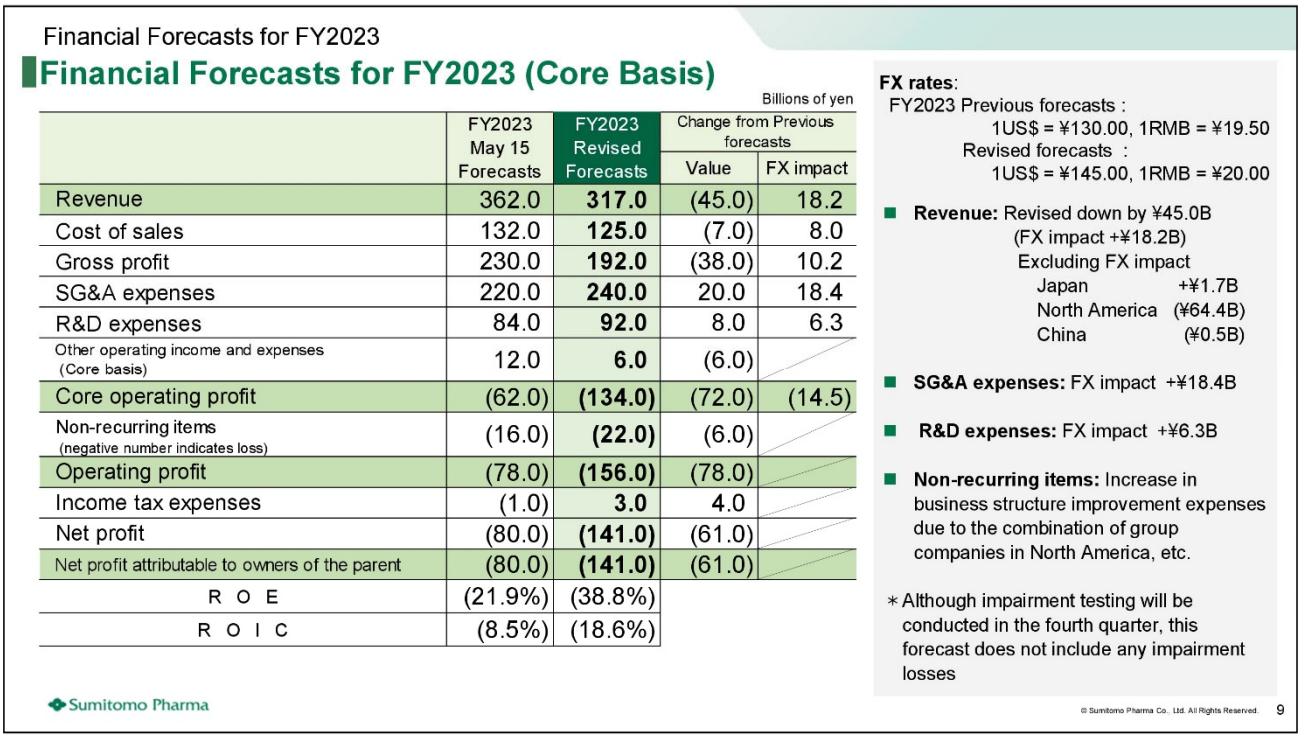
Page seven shows the financial performance by segment.

In each segment, SG&A expenses decreased. However, due to the decline in gross profit from decreased revenue, each segment experienced a reduction in profits.



Please refer to page nine. I will explain the revisions to the full-year financial forecasts.

Revenue is forecast to be JPY317 billion, a decrease of JPY45 billion from the previous forecasts. While there is an increase in revenue due to the revised FX rates assumption from JPY130 to JPY145 per US dollar, and JPY19.5 to JPY20 per RMB, the main reason for the downward revision is based on the sales progress of the Three Key Products and LATUDA® in the North America segment.

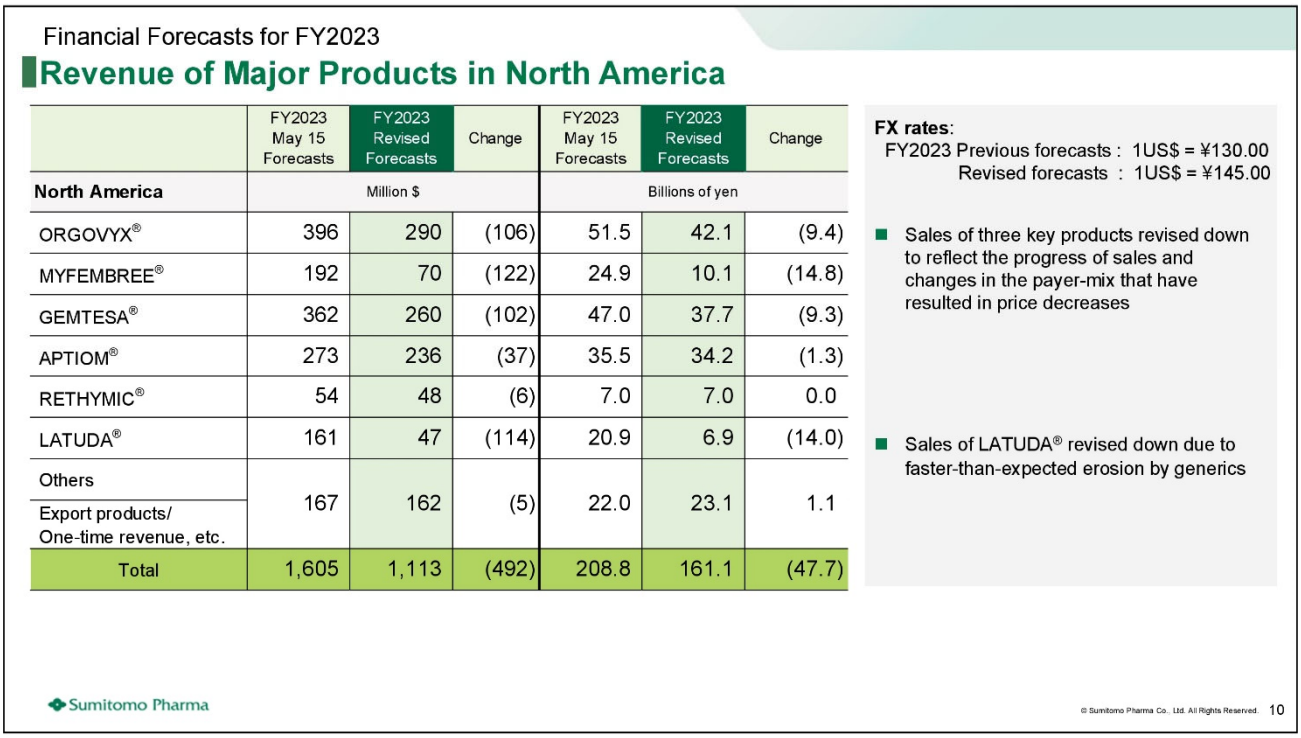
SG&A expenses, as well as R&D expenses, are expected to increase mainly due to the impact of the revised FX rates.

Other operating income within the core has been reduced, after incorporating the outlook as of the end of Q3. As a result, core operating profit is expected to see a reduction of JPY72 billion, forecasting a loss of JPY134 billion.

Regarding non-recurring items, due to higher-than-expected expenses for business structure improvement related to the restructuring of North American group companies, operating profit is expected to decrease by JPY78 billion, forecasting a loss of JPY156 billion.

Financial income is expected to include foreign exchange gains due to the weaker yen. However, profit attributable to owners of the parent is expected to decrease by JPY61 billion, forecasting a loss of JPY141 billion.

Note that this forecasts do not include any impairment losses, although an impairment test will be conducted in Q4 of FY2023.



Financial Forecasts for FY2023

Revenue of Major Products in North America

	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change
North America	Million $			Billions of yen		
ORGOVYX®	396	290	(106)	51.5	42.1	(9.4)
MYFEMBREE®	192	70	(122)	24.9	10.1	(14.8)
GEMTESA®	362	260	(102)	47.0	37.7	(9.3)
APTIOM®	273	236	(37)	35.5	34.2	(1.3)
RETHYMIC®	54	48	(6)	7.0	7.0	0.0
LATUDA®	161	47	(114)	20.9	6.9	(14.0)
Others / Export products/ One-time revenue, etc.	167	162	(5)	22.0	23.1	1.1
Total	1,605	1,113	(492)	208.8	161.1	(47.7)

FX rates:
FY2023 Previous forecasts : 1US$ = ¥130.00
Revised forecasts : 1US$ = ¥145.00

- Sales of three key products revised down to reflect the progress of sales and changes in the payer-mix that have resulted in price decreases
- Sales of LATUDA® revised down due to faster-than-expected erosion by generics

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Please turn to page 10. I will explain the revisions to the financial forecasts for individual products in North America.

The Three Key Products will be discussed in the following slides, but in total, for the Three Key Products, we have reduced the forecast by USD330 million.

For LATUDA®, due to faster-than-expected penetration of generics, we have revised the forecast down by USD114 million, considering the progress to date.

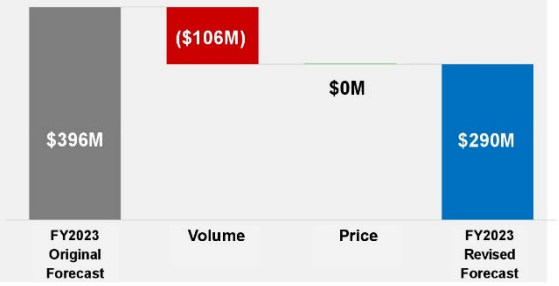
Financial Forecasts for FY2023

Marketing Status of ORGOVYX®

Original plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $215M	
$265M	$215M	81%	Volume	Unfavorable. approx. ($59M)
			Price	Favorable. approx. $9M

- Q3 YTD FY2023 revenue increased approx. 68% compared to Q3 YTD FY2022
- Original plan for Q3 YTD FY2023 was not achieved mainly due to slower than expected market share uptake

Analysis of FY2023 Original Forecast vs Revised Forecast



Future Marketing Strategies

- Promoting combination therapy through the use of publications on combination data, including the results of the combination group sub-analysis of the Phase 3 study (HERO study) of ORGOVYX®
- Educating all stakeholders including Patients/HCPs/Reimbursement representatives on changes to Medicare Part D benefit design (From Jan. 2024, the Medicare Part D benefit design was changed, including eliminating of out of pocket following catastrophic phase and increasing the low income subsidy threshold)
- Utilizing a tool (Video messages from patients taking ORGOVYX® and Discussion Guide) to support meaningful conversations with patients and their physicians on treatment options

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Page 11 discusses the marketing status of ORGOVYX®. Against the Q3 plan of USD265 million, the actual performance was USD215 million, achieving 81%.

The impact of volume and price on the Q3 performance is as detailed, with the impact mainly due to volume.

We have revised the FY2023 forecast from USD396 million to USD290 million. The main reason is that in large university hospitals and hospital groups, which make up about 50% of the market share for androgen deprivation therapy where ORGOVYX® is administered, the acquisition of market share has been less than planned, leading to a reduction in expected volume.

Regarding future marketing strategies, in addition to the activities listed, we will strengthen our efforts by promoting adoption activities through dedicated teams established in July 2023 in university hospitals and hospital groups, which have been a challenge.

Financial Forecasts for FY2023

Marketing Status of MYFEMBREE®

Myfembree® (relugolix, estradiol, and norethindrone acetate) tablets 40 mg, 1 mg, 0.5 mg

Original plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $49M	
$116M	**$49M**	**43%**	Volume	Unfavorable. approx. ($58M)
			Price	Unfavorable. approx. ($9M)

- Q3 YTD FY2023 revenue increased approx. 133% compared to Q3 YTD FY2022. TRx and NBRx share* in uterine fibroids (UF) and endometriosis (EM) of GnRH antagonists market are 42% and 48% in Dec. 2023 (30% and 40% in March 2023)
- Original plan for Q3 YTD FY2023 was not achieved mainly due to slower than anticipated GnRH class growth in both UF and EM, and slower than expected market share uptake in EM

*Source: Symphony METYS – Data through December 2023, IDV®

Analysis of FY2023 Original Forecast vs Revised Forecast

Future Marketing Strategies

- Optimizing the appeal of GnRH therapy as treatment of choice after first oral contraceptive failure for both UF and EM
- Ensuring that patients with UF and EM are aware of MYFEMBREE® by DTC including SNS
  (Utilizing Endometriosis Awareness Month in March 2024)
- Improving market access in UF and EM, and increasing awareness of appropriate timing of start dosing for successful treatment

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Page 12 discusses the marketing status of MYFEMBREE®. Against the Q3 plan of USD116 million, the actual performance was USD49 million, achieving 43%. The impact on the Q3 performance is mainly due to volume, as detailed.

The FY2023 forecast has been revised from USD192 million to USD70 million. The primary reasons are the significant impact of volume, the slow expansion of the GnRH antagonist market for uterine fibroids, and insufficient market share expansion in endometriosis.

For future marketing strategies, we will improve our appeal messages to position MYFEMBREE® as the first treatment option for cases where oral contraceptives are ineffective for uterine fibroids and endometriosis. We will utilize DTC, including social media, to raise awareness among patients who are potential candidates for MYFEMBREE®.

Financial Forecasts for FY2023

Marketing Status of GEMTESA®

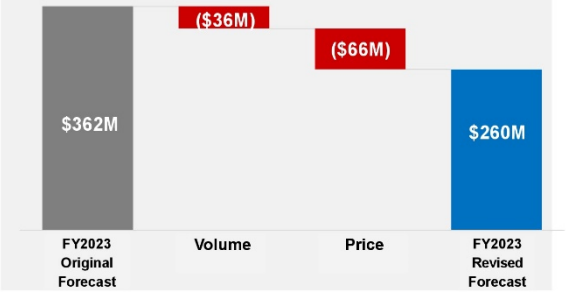
Original Plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $174M	
$246M	**$174M**	**71%**	Volume	Unfavorable. approx. ($25M)
			Price	Unfavorable. approx. ($47M)

- Q3 YTD FY2023 revenue increased approx. 39% compared to Q3 YTD FY2022. TRx and NBRx Share* in Beta3 are 23% and 33% in Dec. 2023 (16% and 28% in March 2023)

* Source IQVIA NPA

- Original plan for Q3 YTD FY2023 was not achieved mainly due to price down by higher proportion of Medicare Part D prescriptions

Analysis of FY2023 Original Forecast vs Revised Forecast



Future Marketing Strategies

- Optimizing structure and effectiveness of the sales team to strengthen the primary care market
- Strengthening to educate HCPs on the differentiated clinical profile of GEMTESA®, including safety for OAB patients with hypertension
- Enhancing the provision of GEMTESA® information to payors to maintain and improve market access for patients to continue to have affordable access

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Page 13 discusses the marketing status of GEMTESA®. Against the Q3 plan of USD246 million, the actual performance was USD174 million, achieving 71%. The impact on the Q3 performance is mainly due to price, as detailed.

The FY2023 forecast has been revised from USD362 million to USD260 million. The main reasons are the worsening price situation due to an increased proportion of prescriptions under Medicare Part D and a reduction in volume due to insufficient market share acquisition.

For future marketing strategies, we will optimize our sales team and activities, including increasing representatives focused on the primary care market, to promote prescription efforts in this area.

Additionally, we will strengthen the provision of information to healthcare professionals about GEMTESA®'s product characteristics, including its safety for patients with overactive bladder who have hypertension, as GEMTESA® has minimal impact on blood pressure.

Financial Forecasts for FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2023 Revised Forecasts	Revenue	115.8	161.1	40.1	317.0
	Cost of sales	55.2	59.4	10.4	125.0
	Gross profit	60.6	101.7	29.7	192.0
	SG&A expenses	47.4	180.6	12.0	240.0
	Core segment profit	13.2	(78.9)	17.7	(48.0)
	R&D expenses				92.0
	Core operating profit				(134.0)
FY2023 May 15 Forecasts	Revenue	114.1	208.8	39.1	362.0
	Cost of sales	54.2	68.8	9.0	132.0
	Gross profit	59.9	140.0	30.1	230.0
	SG&A expenses	47.7	160.3	12.0	220.0
	Core segment profit	12.2	(20.3)	18.1	10.0
	R&D expenses				84.0
	Core operating profit				(62.0)
Change	Revenue	1.7	(47.7)	1.0	(45.0)
	SG&A expenses	(0.3)	20.3	(0.0)	20.0
	Core segment profit	1.0	(58.6)	(0.4)	(58.0)
	R&D expenses				8.0
	Core operating profit				(72.0)

Japan
- Profit expected to increase due to increase in revenue

North America
- Profit decreased due to the significant impact of the downward revision of revenue

Asia
- Profit decreased due to the impact of the downward revision of revenue in local currency

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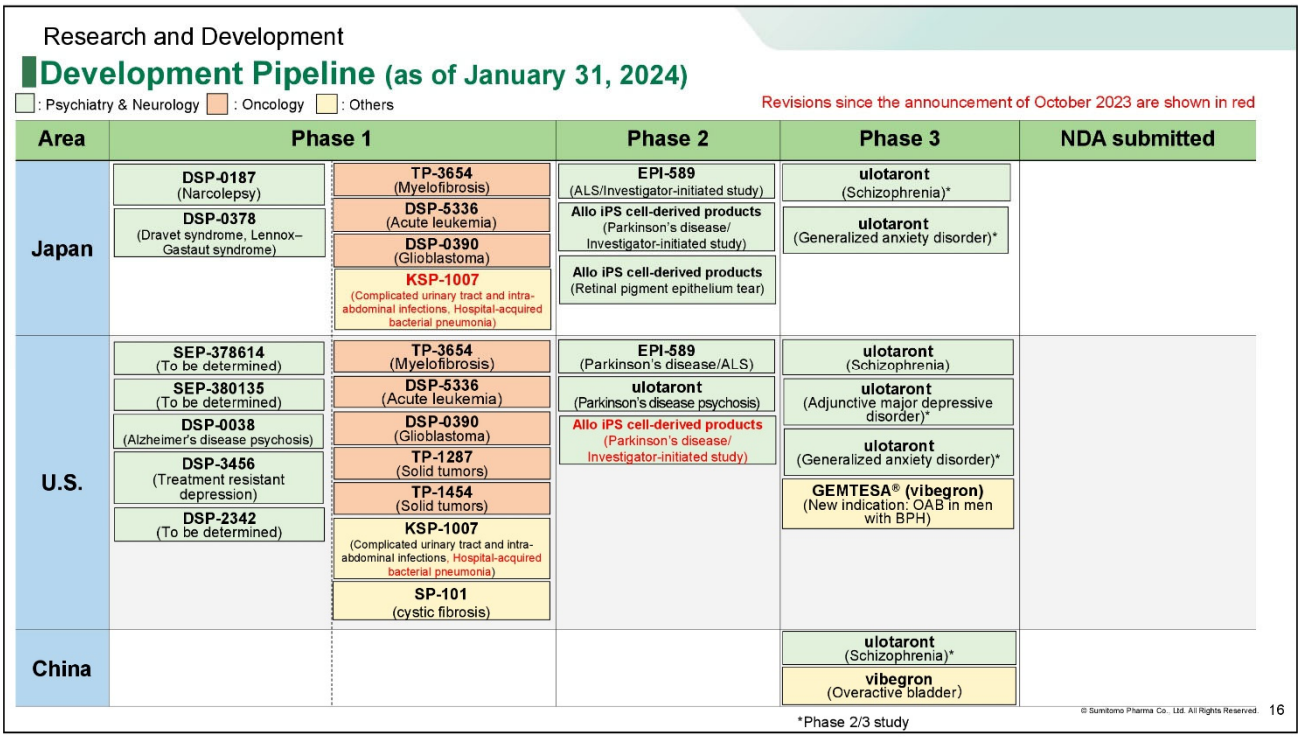
Page 14 presents the financial forecasts by segment.

In the Japan segment, due to the upward revision in revenue, core segment profit is expected to increase by JPY1 billion compared to the previous forecast.

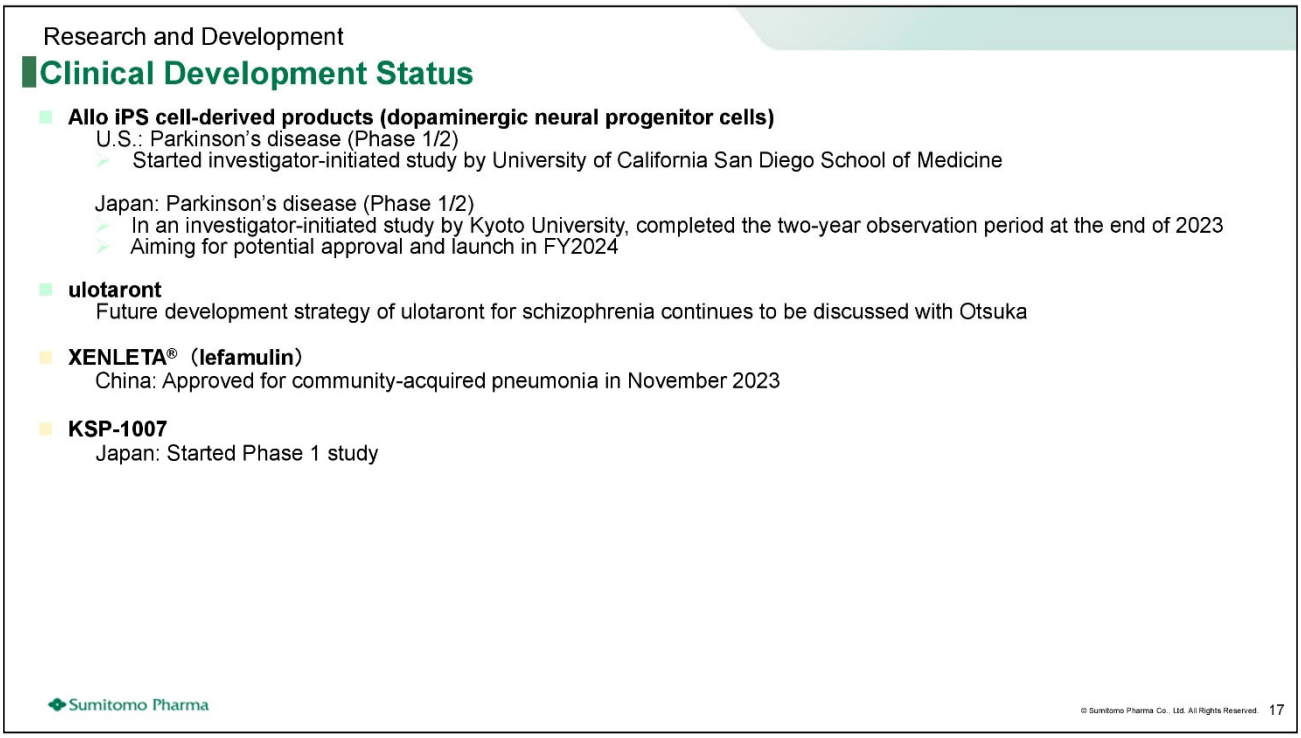
In the North America segment, the significant impact of the downward revision in revenue on gross profit is expected to lead to a decrease in core segment profit of JPY58.6 billion compared to the previous forecast.

In the Asia segment, excluding the impact of FX rates, revenue is revised downward. This is mainly due to the low performance of LATUDA® in China, and as a result, core segment profit is expected to decrease by JPY0.4 billion compared to the previous forecast.



Ikeda: Please turn to page 16. From here, I will explain the development status.

This table is an overview of the development stages of our pipeline compounds. Changes since October last year will be explained on the next page.



Please look at page 17. Here we summarize the progress in clinical development.

In the Psychiatry & Neurology area, a Phase 1/2 study conducted by the University of California San Diego School of Medicine, using allogeneic iPS-cell derived dopaminergic neural progenitor cells, has begun in the U.S. We are funding this investigator-initiated study and providing the cells for transplantation. The study data will be used for future development in the U.S.

In Japan, an investigator-initiated study is also being conducted at Kyoto University, and the two-year observation period ended at the end of 2023. Using the results of this study, we aim to obtain an approval and launch the product in Japan in FY2024.

We expect that transplantation of this product will improve motor functions in patients with Parkinson's disease, contributing to the extension of healthy life expectancy. It offers a completely new treatment mechanism different from existing medications to patients with Parkinson's disease. We aim for it to become a blockbuster in the 2030s.

Regarding ulotaront, we are continuing to discuss future development strategies for schizophrenia with Otsuka Pharmaceutical Co., Ltd.

In Other areas, XENLETA® was approved in China for community-acquired pneumonia in November last year.

For KSP-1007, we have initiated a new Phase 1 study in Japan.

Research and Development

Allogeneic iPS cell-derived Dopaminergic Neural Progenitor Cells Started Investigator-Initiated Study in the U.S.

Overview of this clinical study

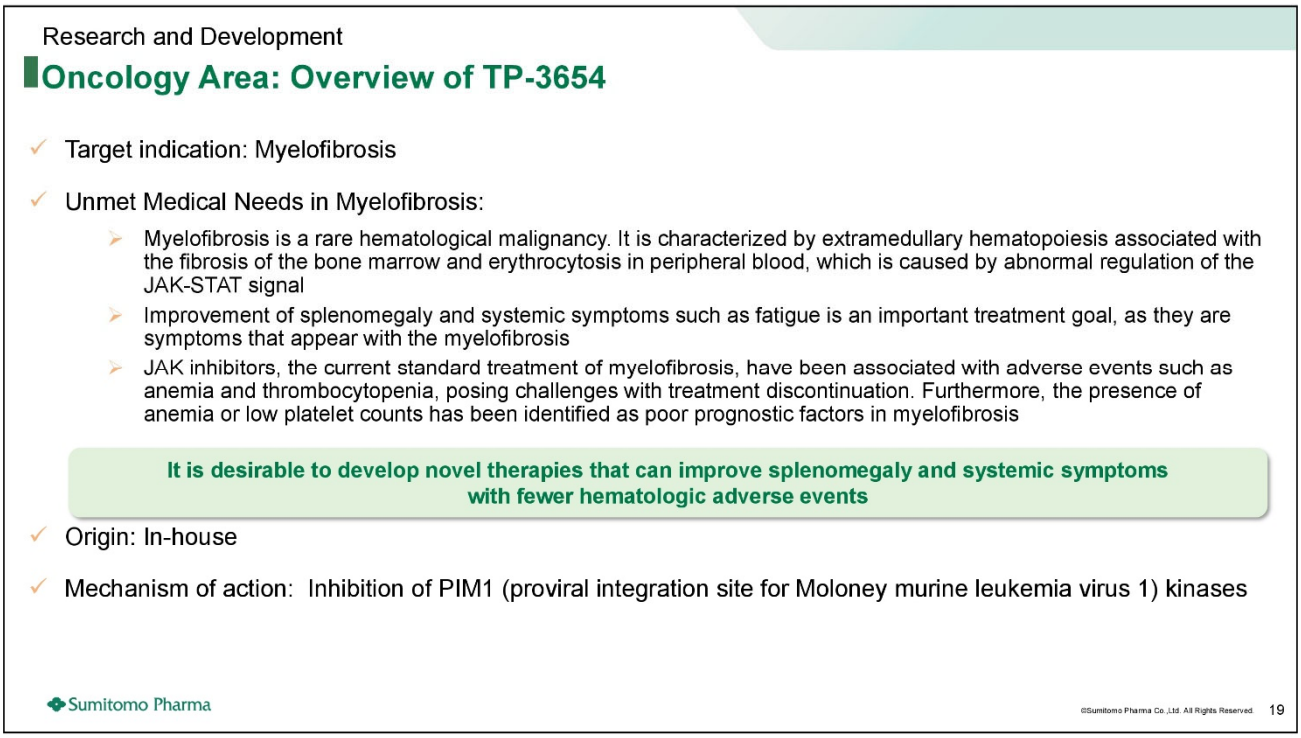
Test product	Allogeneic iPS cell-derived dopaminergic neural progenitor cells (CT1-DAP001)
Development stage	Phase 1/2
Study patients	Patients with Parkinson's disease
Study design (Target number of patients)	Single center, open, non-placebo-controlled (Seven patients)
Primary endpoint	Safety: Frequency and severity of adverse events
Secondary endpoint (Efficacy)	Motor symptoms and others

The role of each organization, etc.

- ✓ Clinical study institution: The Sanford Stem Cell Institute CIRM Alpha Clinic at University of California San Diego School of Medicine
- ✓ Provided cell: Allogeneic iPS cell-derived dopaminergic neural progenitor cells (derived from QHJI donor-iPS cells, provided by the iPS Cell Stock Project of CiRA Foundation)
- ✓ Technical support: Kyoto University Hospital and a research group led by Professor Jun Takahashi of CiRA
- ✓ Cell manufacturing: Sumitomo Pharma (Produce dopaminergic neural progenitor cells at SMaRT in Japan and transported to U.S.)
- ✓ Financial support: Sumitomo Pharma

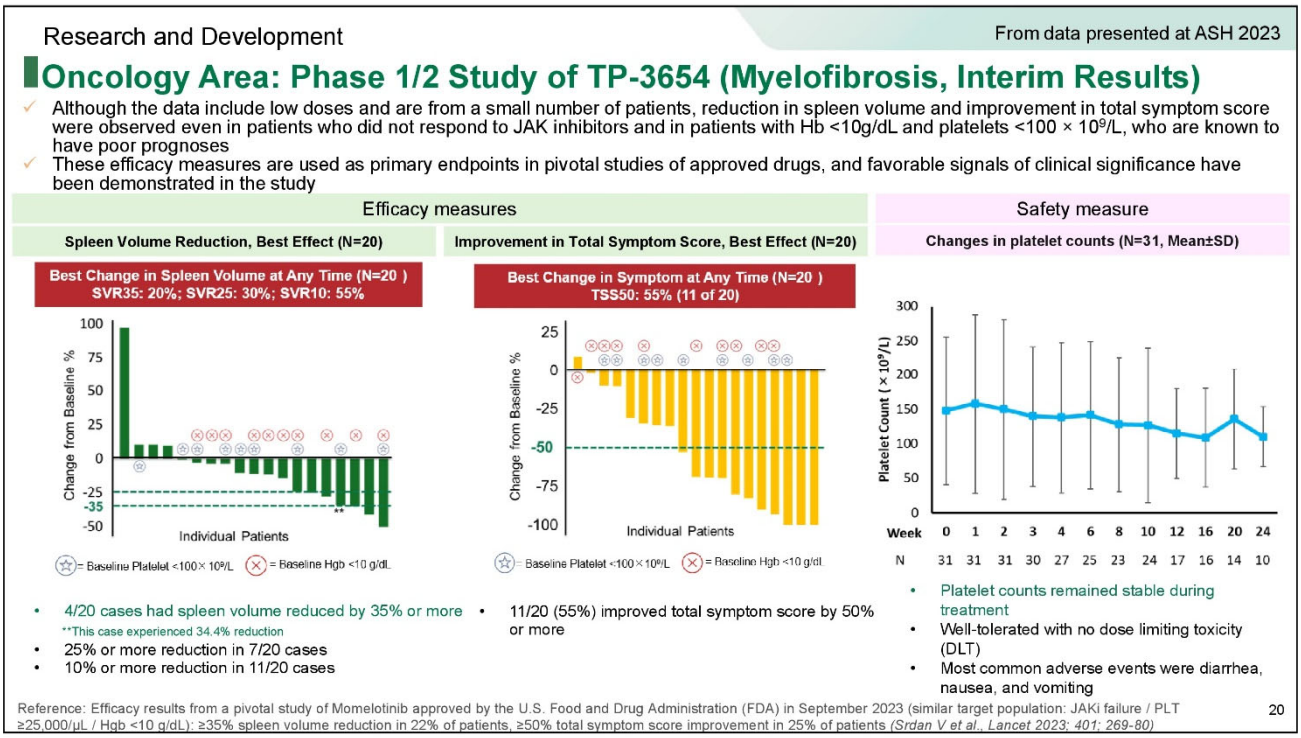
Now, please turn to page 18. Here we show an overview of the investigator-initiated study in the U.S. for allogeneic iPS-cell derived dopaminergic neural progenitor cells.

This study started in November 2023. The raw iPSC was provided by the CiRA Foundation. We differentiate these cells into dopaminergic progenitor cells and then transport them to the U.S.



Page 19 provides an overview of TP-3654, which is under development for myelofibrosis.

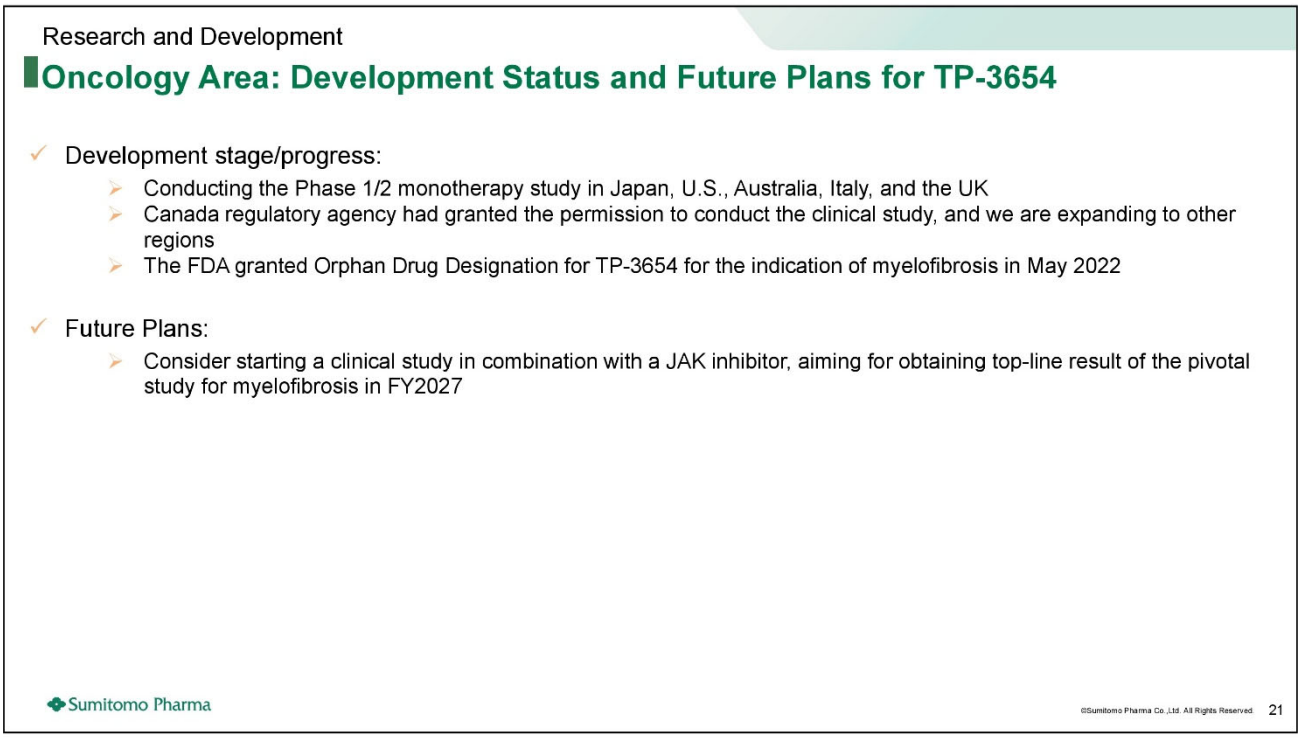
There is a demand for new treatments in myelofibrosis that can reduce splenomegaly and alleviate systemic symptoms with fewer hematological adverse events.



Please turn to page 20. Here we show the interim results of the monotherapy Phase 1/2 study of TP-3654 for myelofibrosis.

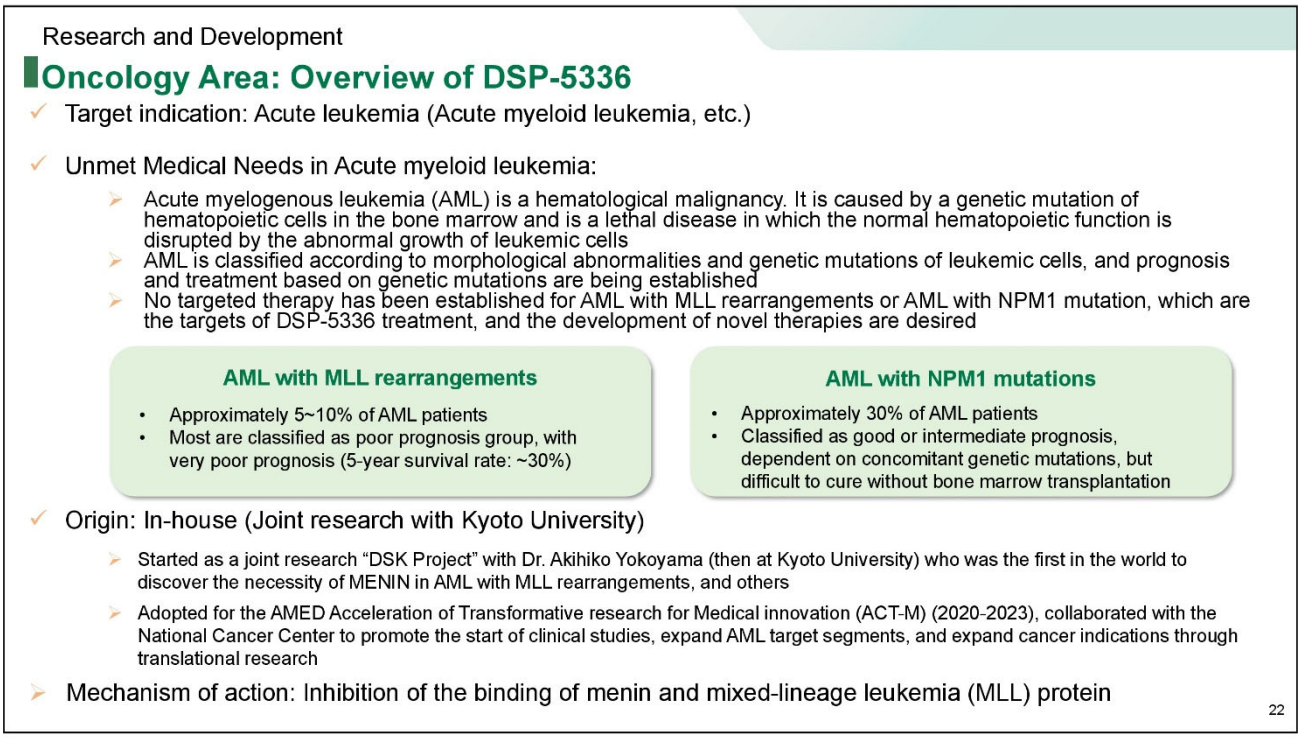
Regarding efficacy, reduction in spleen volume and improvement in symptom scores were observed even in patients who did not respond to JAK inhibitors, as well as in patients known to have a poor prognosis, with hemoglobin levels of less than 10 grams per deciliter and platelet counts of less than 100,000 per microliter.

In terms of safety, platelet counts remained stable during treatment, no dose-limiting toxicities were observed, and tolerability was good. The most common adverse events were diarrhea, nausea, and vomiting.



Please look at page 21. This page shows the development status and future plans for TP-3654.

We are considering initiating a combination study with JAK inhibitors and aim to obtain top-line results of the pivotal study for myelofibrosis in FY2027.



Turn to page 22. Here we provide an overview of DSP-5336, which is under development for acute leukemia.

In acute myeloid leukemia, cases with MLL rearrangements have a poor prognosis, and those with NPM1 mutations are difficult to cure without bone marrow transplantation, underscoring the need for new treatment options.

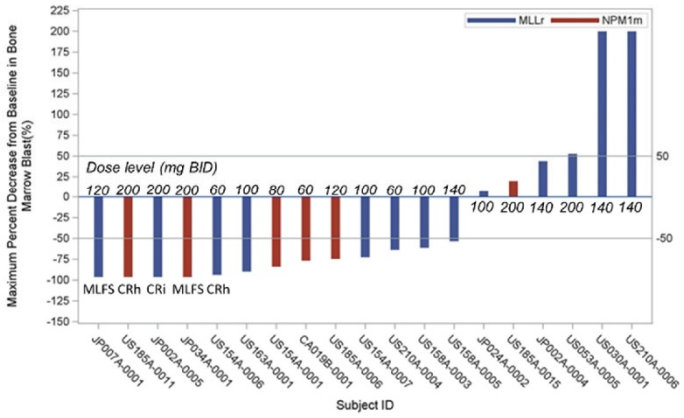
Research and Development

From data presented at ASH 2023

Oncology Area: Phase 1/2 Study of DSP-5336 (Acute Leukemia, Interim Results)

Changes in Bone Marrow Blasts (%)

Patients with MLLr or NPM1m across all dose levels



CRh: clinical remission with partial hematologic recovery
CRi: clinical remission with incomplete count recovery
MLFS: morphologic leukemia-free state

Safety (43 patients)

- ✓ Well-tolerated with no dose limiting toxicity (DLT)
- ✓ Most common adverse events were nausea, vomiting, and fatigue
- ✓ No QTc prolongation or other cardiotoxicity associated with DSP-5336
- ✓ No differentiation syndromes have been observed among patients positive for DSP-5336 target mutations (MLLr or NPM1m)

Efficacy (19 patients with DSP-5336 target mutations, MLLr or NPM1m)

- ✓ Significant bone marrow blasts loss was observed in numerous efficacy-evaluable patients with DSP-5336 target mutations (MLLr or NPM1m)

Sumitomo Pharma

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Please refer to page 23. This page presents the interim results of the monotherapy Phase 1/2 study of DSP-5336 for acute leukemia.

Regarding safety, no dose-limiting toxicities were observed, tolerability was good, and the most common adverse events were nausea, vomiting, and fatigue.

No QTc prolongation or other cardiotoxicity associated with the DSP-5336, and no differentiation syndromes in patients positive for DSP-5336 target mutations, were observed.

In terms of efficacy, a significant decrease in bone marrow blasts was observed in many evaluable patients with DSP-5336 target mutations, and cases of remission have already been observed.

Please turn to page 24. Here we present the development status and future plans for DSP-5336.

Therapeutic options for difficult-to-treat, refractory relapsed acute myeloid leukemia cases are extremely limited. We aim to obtain an approval in a single-arm Phase 2 study without a control treatment. After discussions with regulatory authorities, we plan to start the Phase 2 study in first half of FY2024.

We are targeting the indication of acute myeloid leukemia for approval in Japan and the U.S. in FY2026.

This concludes my presentation.

Noguchi: Thank you, Dr. Ikeda and Mr. Ishida, for your presentations.

Question & Answer

Noguchi [M]: We will now proceed to the question-and-answer session.

Wakao, JPMorgan Securities Japan [Q]: Thank you for the presentation. I have three main questions. First, could you elaborate the potential for impairment of these Three Key Products? You mentioned conducting impairment tests in Q4 of FY2023. Given MYFEMBREE®'s particularly challenging situation and the significant downward revision of its outlook, I believe the likelihood of impairment is quite high.

Additionally, based on today's presentation, ORGOVYX® and GEMTESA® seem to be in a tougher situation than I thought. Should I also consider a heightened risk of impairment for these products?

Nomura [A]: Thank you for your question. Regarding impairment, we are currently reviewing it, so at this stage, I cannot comment specifically on it. It will take some time as we are revising our long-term performance outlook. Based on that, we will properly evaluate and proceed with the process, so I would like you to understand it that way.

Wakao [Q]: Understood. Considering the current situation, should I assume that the long-term outlook for each product has declined? It seems very challenging for them to suddenly achieve a significant upturn and reach the original expectations set by your company.

Nomura [A]: Yes, regarding the sales forecast, for instance, even for FY2024, the level has already decreased compared to what we envisioned for FY2023. In other words, the achievement of sales targets will be delayed. That's how I see it.

Wakao [Q]: I understand, thank you. Another point, regarding expenses for business structure improvement recorded in North America—is my understanding correct that these are new restructuring? If these are indeed new, what level of SG&A expenses can we expect in North America for the coming fiscal year?

Nomura [A]: The business structure improvement in question has already been implemented. As of July 1, 2023, we consolidated about seven companies in North America into one, reducing the number of employees and associated costs in the process. This is what is now reflected as business structure improvement expenses.

From that perspective, as Mr. Ishida explained earlier, while there was a significant increase in SG&A expenses due to FX rates differences, the actual impact wasn't as substantial. In that sense, I believe we have achieved the original plan.

However, given the downside in top-line sales in North America, we will need to continue examining and implementing specific measures for efficient operations in the region.

Wakao [Q]: Understood. Finally, considering what you've shared, I believe the goal was to return to profitability next fiscal year. What are your thoughts on this now?

Initially, there were discussions of increased profits and aiming for profitability, possibly through sales milestones, like with ORGOVYX®, or gains from the sale of LATUDA® rights. However, considering the current situation with ORGOVYX®, it's unclear whether sales milestones will be achieved, and the top-line seems uncertain. Could you clarify whether profitability is still expected?

Nomura [A]: Yes, we are currently discussing the budget, and it's not yet fully fleshed out. As you pointed out, it's certain that we are facing a downside compared to when we set the Mid-term Business plan 2027.

However, we still have a target for core operating profit to be in the black, although the extent of profitability might vary. We remain committed to achieving this target as we work toward the FY2024 budget.

Wakao [Q]: Regarding the sales milestone for ORGOVYX®, do you foresee any issues? Are you expecting to receive it even at the current sales level?

Nomura [A]: As for that, it's still a matter under review, so I can't say anything definitive at this stage. Regardless of the milestone achievement, we are committed to reaching profitability.

Wakao [Q]: Understood. In terms of further reductions in North America, are there plans to implement additional cost-cutting measures in the short term to achieve profitability next fiscal year?

Nomura [A]: Yes, regarding cost reductions, let's say, for example, if investing an additional 1 dollar in marketing brings a return of 1.5 dollars. In such a case, rather than cutting costs, we might increase marketing expenses to boost revenue. We will analyze the relationship between costs, revenue, and profitability before deciding how to allocate resources.

However, our policy of using costs efficiently remains unchanged.

Wakao [Q]: I see. So, are you suggesting that no major structural restructurings are expected?

Nomura [A]: Not necessarily on a large scale, but as I mentioned earlier, our aim is to implement measures that will ensure our core operating profit, regardless of the size of core operating profit, is in the black.

Wakao [M]: Understood. Thank you very much. That's all from me.

Yamaguchi, Citigroup Global Markets Japan [Q]: I apologize if I missed this, but I have a question about the Kyoto University iPS cells investigator-initiated study that concluded at the end of 2023. Could you tell us about the outcome of that?

Kimura [A]: Thank you for your question. The observation period of the study ended in December last year, as announced by Kyoto University. We understand that they are currently working on data locking, so the results will be announced afterward.

Yamaguchi [Q]: So, we should wait for a press release from Kyoto University and then you will introduce the results based on that?

Kimura [A]: Since it is an investigator-initiated study by Kyoto University, the results of the study will be announced by them.

We plan to use these results for our future applications. The results will be shared with us shortly, and we plan to concurrently discuss the next steps with PMDA.

Yamaguchi [Q]: I understand. Do you know if it will be in H1 or H2 of this year, or is it still uncertain and dependent on Kyoto University?

Kimura [A]: Yes, it would be best to ask Kyoto University directly, but as far as we can say, it should be within this year.

Yamaguchi [Q]: Thank you for your response. I have another question about the North America business. There were already several questions about it, but I have a simple one to ask. The forecasts for these Three Key Products were originally made by Myovant Sciences Ltd., and after your acquisition of Myovant, it's evident that there were shortfalls this fiscal year, leading to the revisions made now.

When making forecasts for the next fiscal year and beyond, to maintain investor confidence, it seems necessary for your company to critically evaluate the plans and projections made by Myovant. Considering the significant discrepancies this year, what measures are you taking to ensure more accurate forecasts for the future? Are there plans to integrate your personnel with the Myovant team or any other steps to verify the realism of these projections?

Nomura [A]: Thank you for your question. Just to clarify, the Myovant organization as it was known no longer exists and the marketing leadership has changed, so it's a bit different from before.

Regarding ORGOVYX®, it has significant advantages as an oral GnRH antagonist agent, especially in terms of superiority over injectables, and in aspects like testosterone recovery after stopping treatment.

MYFEMBREE®, too, has its advantages, particularly in mitigating the negative impact on bone density by adding female hormones to the tablet.

Therefore, we had very high expectations for the potential of these two products, which might have led to our sales outlook.

However, since taking over from Myovant and examining various data, we have gained a clearer view of reality while operating these products since July 2023.

For example, in the case of ORGOVYX®, indeed, slightly over 60% of prostate cancer patients prefer oral administration. However, economically, leuprolide has almost no financial burden, whereas ORGOVYX® does have some, presenting a bit of a disadvantage there.

However, we are trying to overcome this barrier by emphasizing the benefits of oral administration, like with ORGOVYX®, and its differentiation compared to injectable GnRH medicines.

Still, this remains a significant barrier in increasing sales, and it's becoming increasingly apparent that it's quite challenging. Nonetheless, we are shifting our strategy to make these barriers more manageable and to make the product more user-friendly.

Regarding MYFEMBREE® as well, most patients initially opt for a low-dose pill, likely due to economic considerations. Given this reality, our strategy is to position MYFEMBREE® as the next choice for those who do not respond well to the low-dose pill. We aim to adopt a more realistic marketing strategy, focusing on grounded forecasting rather than just relying on the potential and expected sales of the drug. This approach should prevent significant discrepancies, like the ones we are currently seeing.

As a task, we have instructed the marketing heads in North America to make their forecasting methods more sophisticated. We are also revisiting and advancing our forecasting mechanisms to ensure more refined and effective planning.

Yamaguchi [Q]: I understand. So, one of the challenges for both drugs has been balancing their benefits against the economic burden for patients, and this has contributed to the discrepancy?

Nomura [A]: Yes, that's correct. At present, this is one of the issues we face.

Another challenge is the lack of penetration of the drug's visibility. For MYFEMBREE®, even after our sales and marketing team in the U.S. conducted extensive outreach, we found that many doctors and patients are still unaware of it. Therefore, we need to enhance awareness through various forms of DTC, beyond just TV commercials.

For ORGOVYX®, even though doctors might want to prescribe it, the slight economic burden on patients often leads to a preference for injectables. We're working on providing more information to doctors to make it easier for them to prescribe ORGOVYX®, emphasizing that many patients prefer oral medication—more than 60%—and informing them about the economic aspects. This effort aims to increase the adoption of ORGOVYX®.

As I mentioned in Q2 of FY2023, we hadn't fully penetrated major hospitals and joint purchasing medical institutions, but we are addressing this separately. We have appointed what we call strategic account managers and have seen some promising results. The growth in these areas, especially in terms of deliveries, has been significantly better compared to others, so we are starting to feel the effectiveness of these strategies.

Yamaguchi [M]: I see. Thank you. That's all from me.

Muraoka, Morgan Stanley MUFG Securities [Q]: I'd like to return to the topic of impairment.

Regarding the impairment in Q4 of FY2023, I would appreciate it if you could inform us about the timing. Is the impairment decision made in March, or April 2024, or do we have to wait until the May financial results for FY2023? Or will there be an announcement before that, indicating that you are adjusting the numbers for this period due to the impairment?

Also, in the event that there is no impairment, I would like to know if you plan to issue a press release or some update. How should we think about the timeline and approach for this? Could you give us some advice?

Nomura [A]: Yes, for example, regarding the impairments in FY2022—like for KYNMOBI®, where we decided to stop its commercial activities—it was a case of 100% impairment, making it relatively straightforward to announce immediately. However, the current situation is different. First, we need to assess whether our forecasts are appropriate.

This requires consideration, including the costs involved and the development of a solid business plan, which means this discussion will take some time. We might not have the results of this evaluation until March or April 2024.

As for whether there will be a press release if there turns out to be no impairment, I'm not quite sure at this moment. That's something we'll try to think about when the time comes. For now, it's difficult for me to provide a definitive answer.

Muraoka [Q]: So, should we expect that if there is any announcement to be made, it would be before the next financial results for FY2023 in May?

Nomura [A]: I believe that has been the process in the past. If there is something significant regarding impairment, we have typically made it public. But as of now, it's still under consideration, so I cannot confirm whether there will definitely be an announcement.

Muraoka [Q]: Earlier in response to Mr. Wakao, JPMorgan Securities Japan of the Q&As, you mentioned that you are revising the long-term outlook. Does this mean that you are considering revising the Mid-term Business Plan 2027 as well, and might this be announced simultaneously when you announce the financial results for FY2023 in May 2024?

Nomura [A]: As you know, even our estimate for FY2023 is already off by about USD300 million for the Three Key Products. As Mr. Wakao asked earlier, will there be a sudden upside in sales that brings us back to the original track? It seems unlikely. If the start is low, the growth trajectory will be delayed in achieving the targets. Therefore, a revision is inevitable.

As for when we would announce such a revision, that's a separate matter. We need to internally determine what our long-term business plan will be. Once we have a clear plan that we can communicate with stakeholders externally, we will make an announcement. At this time, I can't specify when exactly that will be.

Muraoka [Q]: I have a question about the development pipeline, particularly DSP-0187 that was licensed to Jazz Pharmaceuticals plc. I believe it was in November 2023, during Jazz's earnings call, that they mentioned pausing the compound's development due to concerns about safety, specifically related to eyes and heart, despite its effectiveness.

I've noticed that this compound seems to be less highlighted in Jazz's materials lately. Can you share any direction or updates within the scope of what's possible?

Ikeda [A]: Since we've out-licensed this compound to Jazz, it's difficult for us to speak in detail about it. However, we frequently hold joint steering committees with Jazz, and are kept informed about their review status.

They are currently examining the potential risks related to cardiovascular issues and visual impairments, but their intention is to resume and move forward the development of the compound as soon as possible.

Muraoka [Q]: So, is it reasonable to expect that discussions are taking place, perhaps about lowering the dosage to address these adverse events?

Ikeda [A]: Without being able to share specific numbers, we understand that they are considerably refining the balance between the adverse events and the effective dosage. Phase 1 study typically involve increasing the dosage to observe responses and tolerability.

However, given the potential cardiovascular risks and visual abnormalities, it's important to thoroughly understand these aspects and proceed with the studies at an effective dosage. We believe that Jazz is considering these factors as they plan to resume the studies.

Hashiguchi, Daiwa Securities [Q]: I have a question about ulotaront. In the conference on Q2 FY2023 financial results, there was a mention that a policy agreement was expected Q4 of FY2023. However, I didn't see any mention of that timeline in today's explanation. What is your current outlook on this?

Ikeda [A]: Regarding the next steps for ulotaront in schizophrenia, based on the results of the DIAMOND 1 and DIAMOND 2 studies, we continue to discuss with Otsuka Pharmaceutical. Our goal is to determine a direction by the end of FY2023, which is by the end of March 2024 for us, and then make an announcement.

Hashiguchi [Q]: In the conference on Q2 FY2023 financial results, someone from your company suggested possible reasons for the high placebo response. Has there been any further insight or confirmation about these reasons that you can share with us?

Ikeda [A]: We have conducted various analyses, including machine learning, regarding the placebo response. As a result, we have identified certain parameters that could provide hints for planning future development.

Therefore, we are considering these factors in our next protocol, though the details are still under discussion.

Furthermore, the placebo response was high. Apart from biomarkers or parameters, the clinical studies locations had to be changed due to the conflict between Russia and Ukraine. The replacement sites in Serbia and Bulgaria experienced a significantly strong placebo response, contributing to the inability to achieve significant differences overall.

Therefore, we acknowledge that Serbia and Bulgaria, having shown a notably strong placebo response, will be considered for exclusion in any future studies.

Hashiguchi [Q]: Based on these analysis results, is there a possibility of revising the development plans for other indications?

Ikeda [A]: Regarding other indications, Otsuka Pharmaceutical is primarily responsible for the adjunctive MDD studies.

For GAD, we are the main party conducting the study. In the case of Otsuka Pharmaceutical, they have not included Russia and Ukraine from the beginning. Additionally, GAD studies differ somewhat from schizophrenia, so we also have not included these countries in our studies.

Furthermore, we do not plan to include countries like Serbia and Bulgaria in our future studies. So, we do not anticipate major revisions regarding the countries involved in our future studies.

Sakai, UBS Securities [Q]: Given the current financial results and the responses in this Q&A session, I can't help but express concern.

If I were a stakeholder in your company, I would be worried, especially considering that Sumitomo Chemical Co. Ltd., your major shareholder, is also facing challenging times. How do you, President Nomura, personally perceive this situation?

In the conference on Q2 FY2023 financial results, when asked if you were considering a Plan B, you said you weren't at that time. Today, however, it seems you are heading in the direction of revising the medium- to long-term outlook. To be clear, when do you foresee a scenario of recovery? You said the timing of announcing changes to the mid-term outlook is uncertain, but without clarity on this, stakeholders might find it difficult. What are your thoughts?

Nomura [A]: Regarding whether everything is okay, these Three Key Products fell short by about USD100 million each FY2023. They are products that are supposed to grow year by year.

We benefitted greatly from LATUDA®, which had sales of USD2 billion, but that is now gone. We had hoped these Three Key Products would drive our growth in the interim, but their growth hasn't met our expectations. As I mentioned earlier, our sales forecasts may have overly relied on their potential.

However, if the Three Key Products grow steadily to a certain level, which will be defined by our future Mid-term Business planning, I believe they will eventually reach a stable phase. So, I'm not too pessimistic.

Nevertheless, the current core operating loss does raise financial concerns. We have various debts, and we are in discussions with our main bank about these issues.

Hashimoto, SMBC Nikko Securities [Q]: As a credit analyst, I'm particularly interested in the company's debt situation, as addressed just now in Mr. Sakai's question.

There are two parts to my question. First, could you provide an overview of the funding outlook for 2024 and 2025, especially regarding the JPY90 billion permanent debt and the potential sale of Roivant Sciences Ltd. shares?

Also, the current price of hybrid bonds has declined quite a bit, about JPY70 or JPY60, falling to levels that suggest concerns about bankruptcy. How do you view the funding outlook, given these factors and the attitudes of financial institutions?

Nomura [A]: Regarding Roivant shares, we plan to sell all of them and use the proceeds to repay our debts.

As for our various debts, as I mentioned earlier, we are in discussions with our main bank regarding these matters.

Hashimoto [Q]: I wanted to ask about is the current decrease in the unit price of hybrid bonds. I believe this reflects a significant distortion in the corporate bond market. I don't think your company is going bankrupt, so I see this more as a distortion caused by there being more sellers than buyers. Do you think it's necessary for your company to implement measures to support this? If so, what measures are you considering?

For example, I believe Sumitomo Chemical is currently considering structural reforms, and since your company is core, could you announce a commitment that you won't be included in those reforms? Or, considering our group company is your main bank, it's difficult to say, but perhaps securing something like a hybrid loan from the main bank? Are you considering any measures to reassure corporate bond investors by increasing the unit price of hybrid bonds, or do you think such measures are unnecessary? What are your thoughts on this?

Nomura [A]: Regarding the decline in the price of both our bonds and stocks, we are very sorry for the inconvenience caused to our investors.

However, at this stage, there's nothing specific we can announce, as no decisions have been made in this regard.

Ishii, Iyakutsushin [Q]: I would like to ask President Nomura about the expectations for the cancer treating compounds, which are currently in development for myelofibrosis and acute leukemia, respectively.

Nomura [A]: We have been working on oncology treatments since around 2011, so it's been about 12 or 13 years. During this time, we have faced challenges, and not everything has gone smoothly.

However, we now have these two compounds, TP-3654 and DSP-5336, which are showing strong evidence at this stage. We are committed to bringing these to market within the Mid-term Business Plan 2027, by FY2027. For DSP-5336, specifically, we're aiming for approval in Japan and the U.S. in FY2026.

Especially with DSP-5336, as it targets a disease with few treatment options, we hope to make a significant contribution. Successful development of these compounds could be a major milestone for our oncology business and give momentum to our subsequent programs.

We are very eager to make a meaningful contribution, particularly to patients with hematological malignancies.

Ishii [Q]: Also, the R&D expenses have increased from JPY84 billion to JPY92 billion. Is there a particular reason for this increase?

Ishida [A]: The increase in R&D expenses is mainly due to the impact of foreign exchange rates. We have revised our assumed exchange rates, and that is the primary factor for this increase.

Ando, Nikkei Inc. [Q]: First, regarding the investigator-initiated study using iPS cells for Parkinson's disease that has started in the U.S., I understand it's an investigator-initiated study. Could you explain why you chose this approach?

Also, as these cells are currently being brought from Japan, and considering the completion of your cell processing center in the U.S., which I believe will also produce iPS cell-derived products, do you have plans to use this cell processing center in the future?

Kimura [A]: Regarding your first question about why we chose an investigator-initiated study, as you know, regenerative medicine requires a quite different setup from typical clinical studies, including how to transplant the cells.

Therefore, we chose this format, prioritizing the transfer of the established system at Kyoto University to the U.S. This allows for direct communication between academia, with University of California San Diego School of Medicine and Kyoto University having a close collaboration agreement.

Regarding the actual costs of the study and the provision of cells, we are providing all of these. We are also supporting the IND application.

As for the production of the cells, we plan to manufacture them at our plant in Osaka and airlift them to University of California San Diego School of Medicine for this study. In the future, we might use the new cell processing center in North Carolina, which is currently being constructed for the cell processing center for iPS cells, depending on the product and circumstances.

Ando [Q]: So, by conducting an investigator-initiated study, the process can actually be expedited, correct?

Kimura [A]: Exactly. If it were a corporate study, we would need to explain the administration methods, which in this case involves drilling into the skull to transplant the cells. Having the doctors from Kyoto University, both from surgeons and physicians, actively discussing and sharing information directly with University of California San Diego School of Medicine, has been very beneficial. We believe this has been the right choice, as the collaboration has been progressing smoothly.

Ando [Q]: Regarding the North Carolina cell processing center, the iPS cells part is currently under construction, right? So, it's not yet completed?

Kimura [A]: The RETHYMIC® part of the cell processing center was completed in August 2023, and the iPS cells part is currently under construction. It's not a separate building, but more like an extension under the same roof.

Ando [Q]: When is it expected to be completed?

Kimura [A]: It should be completed soon, but it's a bit difficult to specify an exact date. However, it won't be too far in the future.

Ando [Q]: So, it will be completed before the next cold season?

Kimura [A]: Yes, that's right.

Ando [Q]: If I may, about the RPE cells, for retinal pigment epithelium tear. You mentioned it was about to start. What is the progress on that?

Kimura [A]: The preparation for the clinical study is progressing smoothly. The first surgical site will soon be open, possibly in February 2024. Once the site is open, we will start calling in patients, or rather, begin patient enrollment. That will be the initial site, and from there, we plan to gradually expand in parallel.

Ando [Q]: The enrollment of the first patients at this surgical site could begin as early as February 2024?

Kimura [A]: To be precise, we will be ready to start enrolling patients in February 2024. However, as it's a rare disease, the exact timing of patient arrival is not within our control.

Ando [Q]: Once you find a patient, you're already set up to start immediately at a specific site?

Kimura [A]: Yes, that's correct. We have already opened hospitals, mainly university hospitals, around the surgical site where patients can be examined and referred for surgery. We will proceed with a hub-and-spoke model.

Ando [Q]: Will you disclose where this site is at the time enrollment begins?

Kimura [A]: Yes, that's right.

Ando [M]: Understood, thank you very much for your answers.

Kume, The Yomiuri Shimbun [Q]: I would like to revisit the topic of the substantial downward revision of JPY61 billion. What led to such a significant revision in Q3 of FY2023? Was it an overly optimistic outlook, stronger-than-expected competition from generic drugs, or was the underperformance of the Three Key Products more severe than anticipated? Could you elaborate on the factors behind this revision?

Nomura [A]: First of all, regarding the Three Key Products, our sales forecast was indeed very optimistic, largely based on the expected potential of these products.

In the actual marketing phase, we encountered various barriers related to prescribing and patient access, which need to be addressed one by one. This process takes time.

Regarding LATUDA®, forecasting sales after the LOE is a bit unusual, but we had some expectations based on its scale. There were also adjustments, like settlements and rebates of FY2022, that contributed to the downward revision.

We have had many products in the past that faced generic competition after LOE, but none with the scale of sales like LATUDA®, where more than 20 generic companies entered the market. Perhaps we were not able to fully assess the impact of this competition.

Kume [Q]: As discussed by the analysts earlier, you mentioned that you are revising the long-term sales outlook. Is it still possible to aim for profitability in the long run? If so, what are the key factors that will drive such a turnaround?

Nomura [A]: The issue with the Three Key Products is that their growth is slower than we expected. These products are not going to remain at their current levels but are expected to grow. Once these Three Key Products reach a certain level, they should contribute to turning our bottom line into a profit.

However, the exact timing of achieving this scenario will require us to redraw our business plans and reassess our cost structures. So, that's what we're currently working on.

I want to reiterate that I'm not saying these Three Key Products are failures. They are just growing slower than we had anticipated. Once they reach a certain level, our business should be able to become profitable.

Additionally, with promising evidence in the regenerative medicine/cell therapy business and the Oncology area, if these areas perform well, their sales revenue could supplement the Three Key Products, further enhancing our financial position.

Misumi, Nikkei Inc. [Q]: It seems that the available cash is becoming a concern.

Looking at the borrowings, there seems to be a significant increase, so I'm wondering if you have managed to stop the bleeding for now. Considering the current financial results, how do you plan to manage future cash flows, especially regarding the attitude of financial institutions and the planned sale of stocks, which might not necessarily be sold at book value? Could you please elaborate on your strategy for managing cash flow?

Nomura [A]: We plan to sell our Roivant shares. Given that these shares are not frequently traded, the sale will likely be spread over a certain period. We don't intend to sell these shares at a low price; our aim is to sell them as high as possible.

Regarding other borrowings, as I said earlier, we are in discussions with our main bank, and that's all I can say at this moment.

Misumi [Q]: Earlier, you mentioned that the Three Key Products are expected to grow in the future. However, I might think that if a product is truly effective, it should naturally sell well without needing too many interventions. Could you explain why you believe the Three Key Products will grow and what your strategy is for this growth?

Nomura [A]: Yes, even if it's a good product, its growth isn't always immediate; there are challenges. For instance, with ORGOVYX®, we're talking about the area of injectable treatments for prostate cancer. The introduction of an oral medication in this field is a first. So, in the minds of most treating doctors, injectables are the default option.

However, as I mentioned earlier, more than 60% of patients prefer oral medications over injections. So, there's a gap between what doctors prescribe and what patients prefer. It's necessary to bridge this gap, and if doctors are hesitant to prescribe oral medications, fearing they might impose financial burdens on patients, we can provide information to alleviate these concerns. Therefore, changing prescribing habits will take time.

Regarding MYFEMBREE®, whether for uterine fibroids or endometriosis, most gynecologists in the U.S. are surgeons, so their inclination is toward surgery. However, many patients may still want children, and in such cases, a less invasive treatment like this medication would be preferable.

Thus, there's a need for a shift in the approach to treatment from the doctors' side, and on the other hand, as I mentioned in response to the analyst's question earlier, patients are first introduced to low-dose pills, but there isn't necessarily strong evidence for their effectiveness.

Our role, then, is to diligently inform both doctors and patients about the treatment options available with MYFEMBREE®, aiming to improve patient QOL through prescriptions. The fact is, even if a product is good, there is no guarantee that it will sell well. This is the reality in medical practice, so we are committed to working on this.

As for GEMTESA®, given that mirabegron is very dominant, we are focusing on enhancing our primary care market and increasing the number of sales reps to promote it more effectively. This grassroots effort is essential for the growth of this medication.

This is not unique to the U.S.; the same applies in Japan. Regardless of how much the creators believe in their medication, making it widely accepted is challenging. If it were the only treatment option available, it might be different. However, when there are multiple options, raising awareness and other efforts are necessary.

Misumi [Q]: Because these treatments are so innovative, it's essential to change the mindset of doctors and overcome various procedural barriers?

Nomura [A]: Yes, it's about the doctors' perceptions and procedural aspects. For example, ORGOVYX® falls under Medicare Part D. To prescribe it in a hospital setting, you need to deal with insurance reimbursements under Part D, which can be a barrier, as many practitioners might not be familiar with this process.

So, we need to provide the necessary information to facilitate this and remove various barriers to the prescription of ORGOVYX®. This is the process I'm talking about.

Noguchi [M]: Thank you very much. We conclude Sumitomo Pharma's Q3 financial results briefing for FY2023. Thank you all for participating today.

[END]