Sumitomo Dainippon Pharma Co., Ltd.
Q3 FY2021 Earnings Presentation & Call Transcript

[Date]	January 31, 2022	
[Venue]	Conference call	
[Number of Speakers]	4	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Executive Vice President, CSO
	Hisayoshi Kashima	Senior Director, Finance & Accounting
	Miwako Harada	Senior Director, Corporate Communications

Disclaimer:
This is a summary of the Q3 FY2021 call and clarifies certain information provided. Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group holds approximately 53% of the outstanding shares of Myovant. As a result, Myovant is consolidated into the results. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit https://www.myovant.com/.

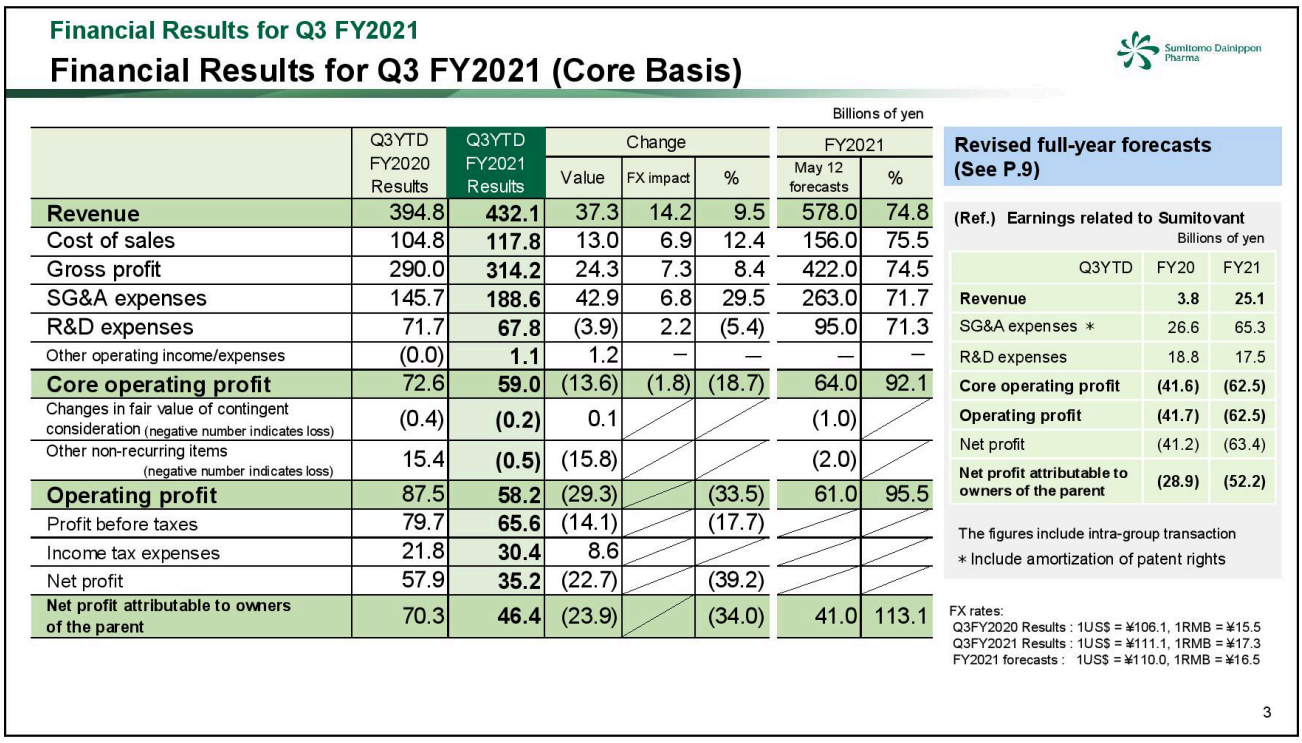
Presentation

Harada: This is Sumitomo Dainippon Pharma Co., Ltd. Thank you very much for taking time out of your busy schedule to participate in our third quarter FY2021 conference call today. I am the moderator, Miwako Harada, Senior Director, Corporate Communications, and today we will share the third quarter business results, FY2021 business forecast, and the status of clinical development efforts.

Presenting today is Mr. Nomura, Representative Director, President and CEO; Dr. Kimura, Representative Director, Executive Vice President, CSO; and Mr. Kashima, Senior Director, Finance & Accounting.

You should have received today's presentation via e-mail. Please feel free to review at your desired pace. The document is also available on our website. There will be a question-and-answer period after the presentation to address any questions you may have. Please note today's conference call is being recorded and a webcast of the discussion, including Q&A, will be posted on our website and accessible in the coming days.

Mr. Kashima will now explain the third quarter business results, FY2021 business forecast, and the current status of clinical development efforts. Mr. Kashima, please.



Financial Results for Q3 FY2021

Financial Results for Q3 FY2021 (Core Basis)

Billions of yen

	Q3YTD FY2020 Results	Q3YTD FY2021 Results	Change			FY2021	
			Value	FX impact	%	May 12 forecasts	%
Revenue	394.8	**432.1**	37.3	14.2	9.5	578.0	74.8
Cost of sales	104.8	**117.8**	13.0	6.9	12.4	156.0	75.5
Gross profit	290.0	**314.2**	24.3	7.3	8.4	422.0	74.5
SG&A expenses	145.7	**188.6**	42.9	6.8	29.5	263.0	71.7
R&D expenses	71.7	**67.8**	(3.9)	2.2	(5.4)	95.0	71.3
Other operating income/expenses	(0.0)	**1.1**	1.2	–	–	–	–
Core operating profit	72.6	**59.0**	(13.6)	(1.8)	(18.7)	64.0	92.1
Changes in fair value of contingent consideration (negative number indicates loss)	(0.4)	**(0.2)**	0.1			(1.0)	
Other non-recurring items (negative number indicates loss)	15.4	**(0.5)**	(15.8)			(2.0)	
Operating profit	87.5	**58.2**	(29.3)		(33.5)	61.0	95.5
Profit before taxes	79.7	**65.6**	(14.1)		(17.7)		
Income tax expenses	21.8	**30.4**	8.6				
Net profit	57.9	**35.2**	(22.7)		(39.2)		
Net profit attributable to owners of the parent	70.3	**46.4**	(23.9)		(34.0)	41.0	113.1

Revised full-year forecasts (See P.9)

(Ref.) Earnings related to Sumitovant

Billions of yen

Q3YTD	FY20	FY21
Revenue	**3.8**	**25.1**
SG&A expenses *	26.6	65.3
R&D expenses	18.8	17.5
Core operating profit	**(41.6)**	**(62.5)**
Operating profit	**(41.7)**	**(62.5)**
Net profit	(41.2)	(63.4)
Net profit attributable to owners of the parent	**(28.9)**	**(52.2)**

The figures include intra-group transaction

* Include amortization of patent rights

FX rates:
Q3FY2020 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
Q3FY2021 Results : 1US$ = ¥111.1, 1RMB = ¥17.3
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

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I would now like to report on our business results for the third quarter of FY2021 and the current status of clinical development based on the presentation materials.

Please see page three. We are pleased to report our business results for the first nine months of the fiscal year ending March 31, 2022.

Revenue increased by JPY37.3 billion or 9.5% YoY to JPY432.1 billion. Sales increased in the North America segment, which benefited from the recognition of USD270 million in revenue from the upfront payment for the alliance with Otsuka Pharmaceutical, and in the China segment, which recovered from the impact of COVID-19. In Japan, sales decreased slightly due to the NHI price revision.

Selling, general and administrative (SG&A) expenses increased due to the full-scale implementation of sales activities at Myovant Sciences Ltd. and Urovant Sciences Ltd., as well as an increase in amortization of intangible assets.

R&D expenses decreased, mainly in oncology and Myovant Sciences.

As a result, core operating profit decreased by JPY13.6 billion to JPY59 billion.

A gain on sale of the Company's Ibaraki plant was recorded in the same period of the previous fiscal year. However, as for other non-recurring items, operating profit decreased by JPY29.3 billion to JPY58.2 billion, as there was no such factor in the current fiscal year.

Profit before income taxes was JPY65.6 billion, a decrease of JPY14.1 billion compared to the same period last year, although it improved compared to operating profit due to the recording of foreign exchange gains from the depreciation of the yen at the end of the third quarter.

As for income tax, the share of income tax expense to income before income taxes for the previous quarter increased due to an increase in losses of the Sumitovant subsidiary, for which no tax effect was recognized.

As a result, net profit attributable to owners of the parent decreased by JPY23.9 billion to JPY46.4 billion.

The full-year forecast has been revised to reflect the situation to date, including the delay in the progress of LATUDA® in North America and the increased expenses. I will explain later.

Financial Results for Q3 FY2021

Revenue of Major Products in Japan

Billions of yen

	Q3 YTD FY2020 Results	Q3 YTD FY2021 Results	Change		FY2021	
			Value	%	May 12 forecasts	%
Equa®/EquMet®	31.3	**29.4**	(1.9)	(5.9)	37.4	78.7
Trulicity® *	25.9	**25.8**	(0.1)	(0.5)	38.2	67.4
TRERIEF®	12.7	**12.9**	0.2	1.8	17.9	72.0
REPLAGAL®	10.6	**10.7**	0.1	1.0	13.8	77.2
METGLUCO®	7.2	**6.3**	(0.9)	(12.5)	6.9	91.2
LATUDA®	1.6	**5.0**	3.4	213.0	6.7	75.0
LONASEN® Tape	0.9	**1.5**	0.6	64.3	2.5	61.6
AMLODIN®	5.1	**4.5**	(0.7)	(12.8)	5.0	89.3
AG products	5.9	**7.5**	1.6	27.4	10.1	73.8
Others	17.4	**13.6**	(3.8)	(21.8)	11.5	118.7
Total	118.5	**117.2**	(1.4)	(1.2)	150.0	78.1

Note: Sales of each product are shown by invoice price (* Trulicity® is shown by NHI price)

- 78.1% progress in the segment total is slow considering Q4 sales
- Decrease in Equa® /EquMet® is attributed to NHI price revision
- LATUDA® showing steady growth
- Long listed products in "Others" are higher than forecast "Others" include TWYMEEG® launched in September
- NHI price revision affected (¥5.4B) on Japan segment total

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Please see page four.

Sales revenue in the Japan segment decreased by JPY1.4 billion YoY to JPY117.2 billion, or 78.1% of the forecast. Excluding the impact of the NHI price revision of JPY5.4 billion, sales would have increased.

Sales of Equa®/EquMet® decreased due to the NHI price revision, and progress of Trulicity® has been slow due to competition and the impact of COVID-19, which reduced opportunities to visit the office and change medications. LATUDA® is progressing closely to plan, with significant sales growth. Sales of TWYMEEG®, which was launched in September 2021, are included in the Others row due to its smaller scale.

Financial Results for Q3 FY2021

Revenue of Major Products in North America & China

Sumitomo Dainippon Pharma

	Q3 YTD FY2020 Resuts	Q3 YTD FY2021 Results	Change	Q3 YTD FY2020 Resuts	Q3 YTD FY2021 Results	Change			FY2021		
						Value	FX impact	%	May 12 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billion yen	
LATUDA®	1,513	1,413	(99)	160.5	157.1	(3.4)	7.1	(2.1)	2,004	220.4	71.3
APTIOM®	187	186	(1)	19.8	20.7	0.9	0.9	4.5	249	27.4	75.6
BROVANA®	212	103	(109)	22.5	11.5	(11.0)	0.5	(49.0)	106	11.7	98.1
KYNMOBI®	1	4	4	0.2	0.4	0.4	0.0	152.7	28	3.1	12.9
ORGOVYX®	—	54	54	—	6.0	6.0	0.3	—	792	87.1	70.1
MYFEMBREE®/ RYEQO®	—	8	8	—	0.9	0.9	0.0	—			
GEMTESA®	—	38	38	—	4.2	4.2	0.2	—			
Others	142	449	308	15.0	49.9	34.9	2.3	232.4			
Total	2,055	2,256	201	218.0	250.7	32.7	11.3	15.0	3,179	349.7	71.7
China	Million RMB			Billions of yen					Million RMB	Billion yen	
MEROPEN®	992	1,226	235	15.3	21.2	5.8	2.2	38.1	1,364	22.5	94.1
Others	242	339	97	3.7	5.9	2.1	0.6	56.6	442	7.3	80.2
Total	1,234	1,566	332	19.1	27.0	8.0	2.8	41.8	1,806	29.8	90.7

FX rates:
Q3FY2020 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
Q3FY2021 Results : 1US$ = ¥111.1, 1RMB = ¥17.3
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

- **North America segment**
  Revenue increased y-o-y, slow progress on full-year forecast
- LATUDA® decreased due largely to down-stream inventory destocking and lower price
- BROVANA® decreased due to loss of exclusivity in June
- Revenue from the alliance with Otsuka $270M (¥30.0B) is recorded in "Others"
- **China segment**
  Increased sales by recovering from the effect of COVID-19
  Progress is higher than forecast

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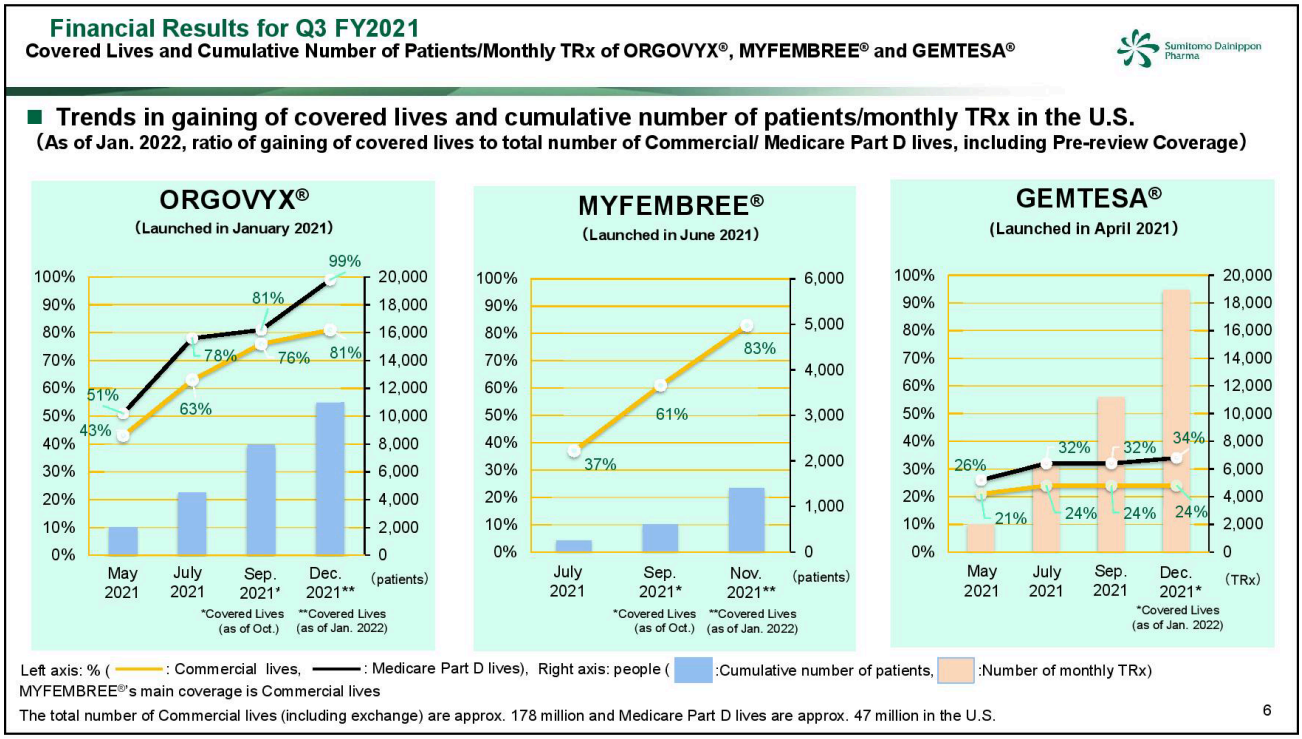
Page five shows sales revenue for the North America and China segments.

Sales revenue in the North America segment was JPY250.7 billion, an increase of JPY32.7 billion compared to the same period in the previous year on a yen basis. The upfront payment from the alliance with Otsuka Pharmaceutical contributed JPY30 billion. In this table, it is included in the Others row.

Sales of LATUDA® were JPY157.1 billion, a decrease of JPY3.4 billion from the same period in the previous year. During the first three quarters of FY2020, shipments increased due to a growing number of prescription days and distribution inventory due to COVID-19, as well as inventory buildup prior to an expected price revision, while the current period saw a relative decrease in volume and average sales price. The progress has been slower compared to the full year forecast at the beginning of the fiscal year.

BROVANA®, for which the exclusive sales period ended in June last year, also saw a significant decrease in sales. Revenue from the alliance with Pfizer and Gedeon Richter for Relugolix is included in the Others row.

The China segment was JPY27 billion, an increase of JPY8 billion. Shipments are recovering from the impact of COVID-19 in the previous fiscal year. The sales, mainly for MEROPEN®, are expected to exceed the full-year forecast.



Page six summarizes the trends in medical insurance coverage and cumulative patient volume/number of prescriptions per month for ORGOVYX®, MYFEMBREE® and GEMTESA®.

Coverage of ORGOVYX® and MYFEMBREE® is growing steadily. As of January 2022, ORGOVYX® achieved 81% coverage in commercial and 99% in Medicare Part D. MYFEMBREE® obtained 83% coverage in commercial. GEMTESA® has not yet grown its coverage as of January but plans to gain significant coverage by the end of 2022.

Financial Results for Q3 FY2021

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q3 YTD FY2021 Results	Revenue (Sales to customers)	117.2	250.7	27.0	7.3	402.2	29.9	432.1
	Cost of sales	61.9	23.6	5.3	4.0	94.8	23.0	117.8
	Gross profit	55.3	227.1	21.8	3.3	307.5	6.8	314.2
	SG&A expenses	38.3	135.6	8.8	1.9	184.7	4.0	188.6
	Core segment profit	17.0	91.5	12.9	1.4	122.8	2.8	125.6
	R&D expenses					67.2	0.6	67.8
	Core operating profit					56.7	2.2	59.0
Q3 YTD FY2020 Results	Revenue (Sales to customers)	118.5	218.0	19.1	11.5	367.1	27.7	394.8
	Cost of sales	59.5	16.3	3.9	4.2	83.8	21.0	104.8
	Gross profit	59.1	201.7	15.2	7.3	283.3	6.6	290.0
	SG&A expenses	36.1	97.2	6.7	2.0	142.0	3.8	145.7
	Core segment profit	23.0	104.5	8.5	5.3	141.4	2.9	144.2
	R&D expenses					71.1	0.6	71.7
	Core operating profit					70.3	2.2	72.6
Change	Revenue (Sales to customers)	(1.4)	32.7	8.0	(4.1)	35.1	2.2	37.3
	SG&A expenses	2.2	38.4	2.1	(0.1)	42.7	0.2	42.9
	Core segment profit	(6.1)	(13.1)	4.4	(3.9)	(18.6)	(0.1)	(18.6)
	R&D expenses					(3.9)	(0.0)	(3.9)
	Core operating profit					(13.6)	(0.0)	(13.6)

- **Japan:** Lower profit due to declined gross profit and increased expenses
- **North America:** Lower profit mainly due to incremental costs related to Sumitovant despite lump-sum revenue from the alliance
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit due to decrease in export

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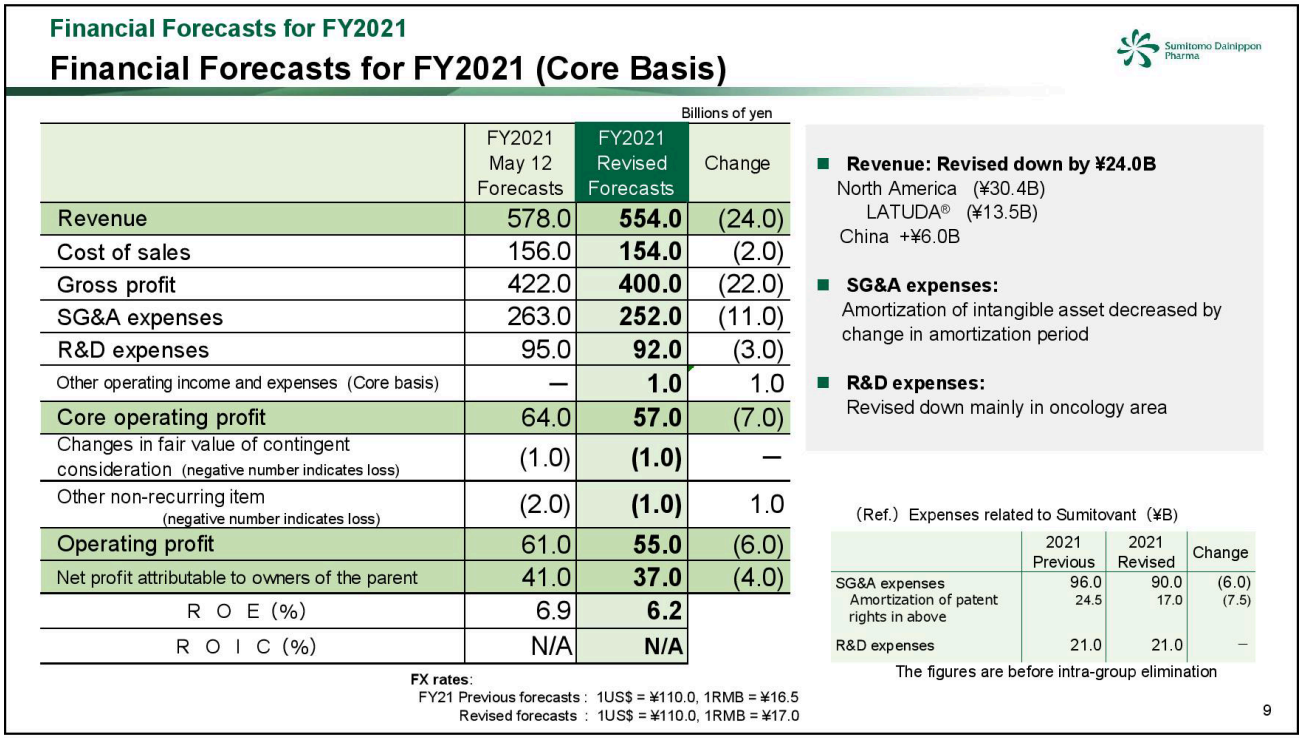
Page seven shows the results by segment.

In the Japan segment, core segment profit decreased by JPY6.1 billion to JPY17 billion due to a decrease in gross profit and an increase in SG&A expenses, including sales expenses for TWYMEEG®, which was launched in September.

In the North America segment, core segment profit decreased by JPY13.1 billion to JPY91.5 billion due to increased selling expenses at Myovant Sciences and Urovant Sciences and increased amortization of intangible assets, despite increased revenue from upfront payment income from alliances.

In the China segment, sales increased significantly, and core segment profit also increased by JPY4.4 billion.



Financial Forecasts for FY2021

Financial Forecasts for FY2021 (Core Basis)

Billions of yen

	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change
Revenue	578.0	**554.0**	(24.0)
Cost of sales	156.0	**154.0**	(2.0)
Gross profit	422.0	**400.0**	(22.0)
SG&A expenses	263.0	**252.0**	(11.0)
R&D expenses	95.0	**92.0**	(3.0)
Other operating income and expenses (Core basis)	—	**1.0**	1.0
Core operating profit	64.0	**57.0**	(7.0)
Changes in fair value of contingent consideration (negative number indicates loss)	(1.0)	**(1.0)**	—
Other non-recurring item (negative number indicates loss)	(2.0)	**(1.0)**	1.0
Operating profit	61.0	**55.0**	(6.0)
Net profit attributable to owners of the parent	41.0	**37.0**	(4.0)
R O E (%)	6.9	**6.2**	
R O I C (%)	N/A	**N/A**	

FX rates:
FY21 Previous forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5
Revised forecasts : 1US$ = ¥110.0, 1RMB = ¥17.0

- **Revenue: Revised down by ¥24.0B**
  North America (¥30.4B)
  LATUDA® (¥13.5B)
  China +¥6.0B
- **SG&A expenses:**
  Amortization of intangible asset decreased by change in amortization period
- **R&D expenses:**
  Revised down mainly in oncology area

(Ref.) Expenses related to Sumitovant (¥B)

	2021 Previous	2021 Revised	Change
SG&A expenses	96.0	90.0	(6.0)
Amortization of patent rights in above	24.5	17.0	(7.5)
R&D expenses	21.0	21.0	–

The figures are before intra-group elimination

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Please see page nine. We would like to explain the revision of the full-year earnings forecast.

Sales revenue is expected to be JPY554 billion, a decrease of JPY24 billion from the previous forecast. This change is driven by reduced revenue expectations mainly in the North America segment for sales of LATUDA® and other products.

SG&A expenses were reduced by JPY11 billion. The main reasons for this were a decrease in amortization expenses for MYFEMBREE® in the current fiscal year due to an extension of the amortization period following the acquisition of a patent for its use, as well as a reduction in sales-related expenses for Sunovion Pharmaceuticals Inc. and other products.

R&D expenses were reduced by JPY3 billion, mainly in the oncology area.

As a result, core operating income is expected to decrease by JPY7 billion to JPY57 billion and operating income is expected to decrease by JPY6 billion to JPY55 billion.

The exchange rate assumptions are JPY110 to the U.S. dollar and JPY17 to the China yuan.

Financial Forecasts for FY2021

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2021 Revised Forecasts	Revenue (Sales to customers)	148.4	319.3	35.8	12.0	515.5	38.5	554.0
	Cost of sales	79.0	31.7	6.9	6.7	124.3	29.7	154.0
	Gross profit	69.4	287.6	28.9	5.3	391.2	8.8	400.0
	SG&A expenses	52.9	179.4	11.7	2.4	246.4	5.6	252.0
	Core segment profit	16.5	108.2	17.2	2.9	144.8	3.2	148.0
	R&D expenses					91.0	1.0	92.0
	Core operating profit					54.8	2.2	57.0
FY2021 May 12 Forecasts	Revenue (Sales to customers)	150.0	349.7	29.8	10.3	539.8	38.2	578.0
	Cost of sales	78.1	38.5	5.5	4.6	126.7	29.3	156.0
	Gross profit	71.9	311.2	24.3	5.7	413.1	8.9	422.0
	SG&A expenses	52.9	191.9	10.9	1.6	257.3	5.7	263.0
	Core segment profit	19.0	119.3	13.4	4.1	155.8	3.2	159.0
	R&D expenses					94.0	1.0	95.0
	Core operating profit					61.8	2.2	64.0
Change	Revenue (Sales to customers)	(1.6)	(30.4)	6.0	1.7	(24.3)	0.3	(24.0)
	SG&A expenses	—	(12.5)	0.8	0.8	(10.9)	(0.1)	(11.0)
	Core segment profit	(2.5)	(11.1)	3.8	(1.2)	(11.0)	—	(11.0)
	R&D expenses					(3.0)	—	(3.0)
	Core operating profit					(7.0)	—	(7.0)

- **Japan segment:** Profit will decrease because revenue down due to decrease in sales and increase in cost of goods
- **North America segment:** Profit will decrease due to decreased sales of LATUDA® despite reduction of SG&A expenses include amortization
- **China segment:** Revenue and profit will increase due to increase of MEROPEN® sales

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Page 10 shows the forecast by segment.

In the Japan segment, core segment profit will be reduced by JPY2.5 billion due to the downward revision of sales of Trulicity® and other products, as well as the recording of valuation losses on some products.

In the North America segment, SG&A expenses will decrease due to the inclusion of lower depreciation expenses and cost savings, but the impact of reduced sales by approximately JPY30 billion in total is significant, resulting in a downward revision of JPY11.1 billion in core segment profit.

In the China segment, sales of MEROPEN® and other products have been revised upward, and core segment profit is also expected to increase by JPY3.8 billion.

Financial Forecasts for FY2021

Revenue of Major Products in Japan

Billions of yen

	FY2021 May 12 Forecasts	FY2021 Forecasts	Change
Equa®/EquMet®	37.4	37.4	–
Trulicity® *	38.2	33.9	(4.3)
TRERIEF®	17.9	16.5	(1.4)
REPLAGAL®	13.8	12.1	(1.7)
METGLUCO®	6.9	8.1	1.2
LATUDA®	6.7	6.7	–
LONASEN® Tape	2.5	2.0	(0.5)
AMLODIN®	5.0	5.5	0.5
AG products	10.1	9.8	(0.3)
Others	11.5	16.4	4.9
Total	150.0	148.4	(1.6)

Note: Sales of each product are shown by invoice price (* Trulicity® is shown by NHI price)

- Revised down by ¥1.6B in the segment total
- Revised down Trulicity® and TRERIEF®
- Revised down REPLAGAL®
  Will terminate sales in February
- Revised up "Others" in line with mainly higher progress of long-listed products

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Page 11 shows the sales forecast by product for the Japan segment.

We have revised downward our previous forecasts of JPY4.3 billion for Trulicity® and JPY1.4 billion for TRERIEF®. Revenue forecast for REPLAGAL®, have been reduced due to the transfer of the manufacturing and marketing approval and the marketing rights in February this year.

On the other hand, we have increased products in the Others row by JPY4.9 billion, mainly reflecting the strong progress in long-term listed drugs.

Financial Forecasts for FY2021

Revenue of Major Products in North America & China

Sumitomo Dainippon Pharma

	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change
North America	Million $			Billions of yen		
LATUDA®	2,004	1,881	(123)	220.4	206.9	(13.5)
APTIOM®	249	239	(10)	27.4	26.3	(1.1)
BROVANA®	106	115	9	11.7	12.6	0.9
KYNMOBI®	28	5	(23)	3.1	0.6	(2.5)
ORGOVYX®	792	663	(129)	87.1	72.9	(14.2)
MYFEMBREE®/ RYEQO®						
GEMTESA®						
Others						
Total	3,179	2,903	(276)	349.7	319.3	(30.4)
China	Million RMB			Billions of yen		
MEROPEN®	1,364	1,635	271	22.5	27.8	5.3
Others	442	470	28	7.3	8.0	0.7
Total	1,806	2,105	299	29.8	35.8	6.0

FX rates:
FY21 Previous forecasts: 1US$ = ¥110.0, 1RMB = ¥16.5
Revised forecasts: 1US$ = ¥110.0, 1RMB = ¥17.0

- **North America**: Revised down by ¥30.4B
- Revised down LATUDA® due to down-stream inventory destocking and assumed lower price
- Revised down APTIOM® and KYNMOBI®
- Revised down "Others" including such as the alliance revenue (Approx. ¥11B) included in the first forecasts of FY2021
- **China:** Revised up MEROPEN® and other

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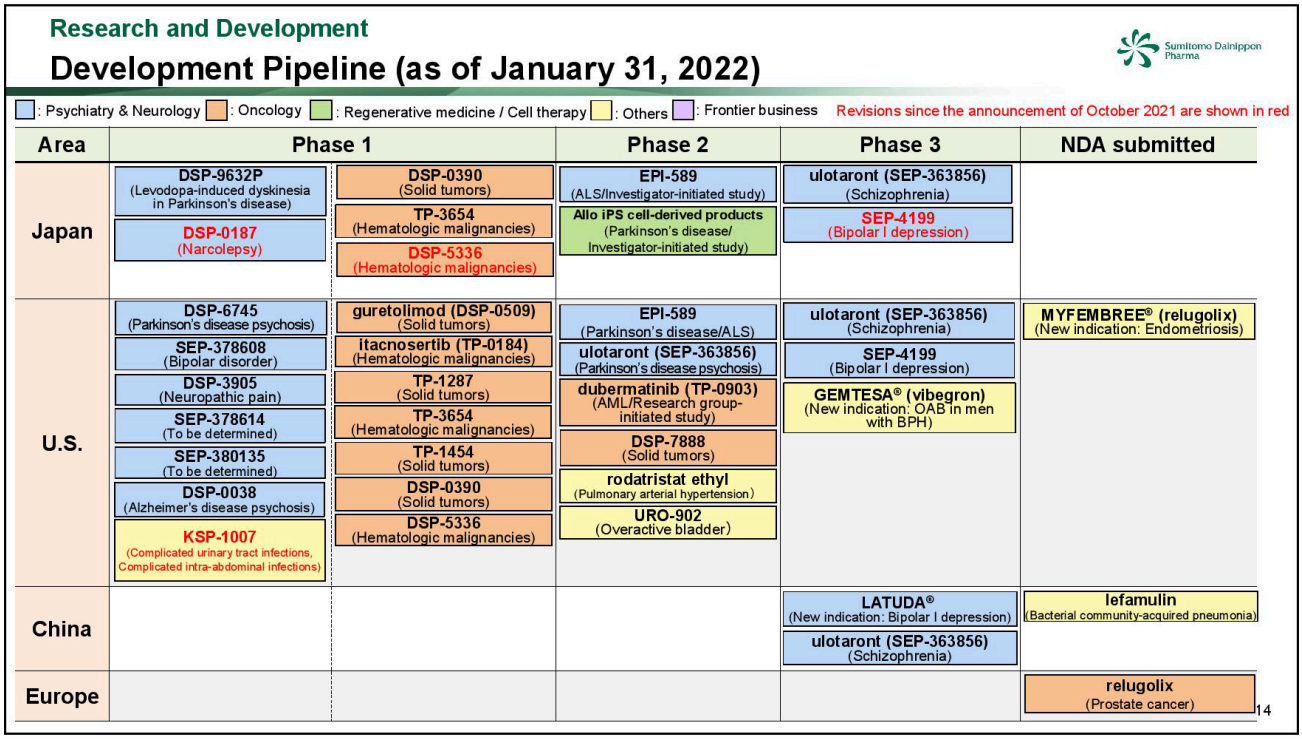
Page 12 shows the sales revenue forecast for the North America and China segments.

Although the inventory situation has been resolved, LATUDA® sales has not been able to make up for the delay until the second quarter, and the effect of lower unit prices in Medicaid and other areas has led to a downward revision of JPY13.5 billion from the previous forecast.

In addition, we have revised downward our other sales revenue by JPY14.2 billion. Aligned with the Mid-term Business Plan, we have been actively pursuing alliances and have factored in revenue from alliances as an approximate number, but we have revised the revenue from alliances as the total revenue from alliances is now solidifying. A negative impact on sales of about JPY11 billion and on core operating income of about JPY6 billion will be seen.

In China, MEROPEN® which was not subject to the centralized purchasing system during the current fiscal year, has been revised upward by JPY5.3 billion.



Please see page 14. I will explain the development status.

This table lists the development stages of our development items. The changes from last October are shown in red and will be explained on the next page.

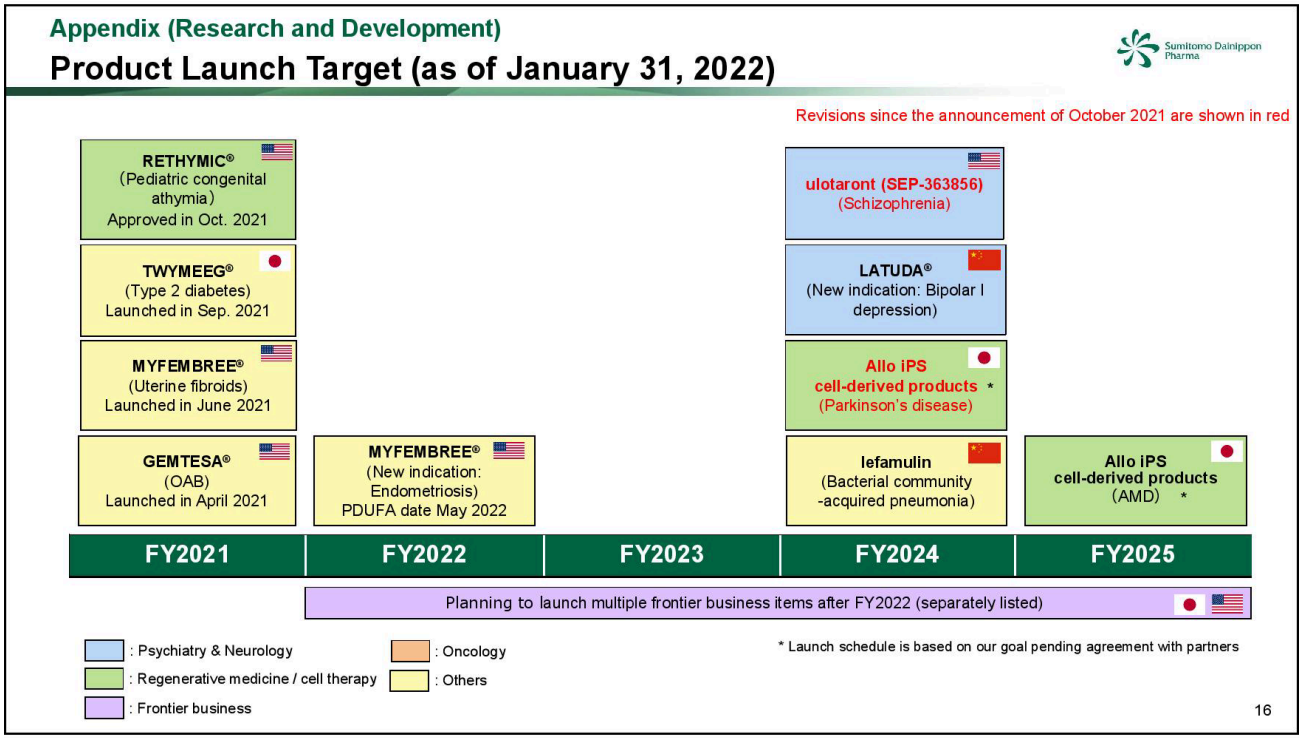
Please see page 15. The following is a summary of the changes made since last October.

In the area of psychiatry and neurology, Japan, in addition to the U.S., has joined the global Phase III program of SEP-4199 for bipolar I depression and has initiated the Phase III study.

Phase I study of DSP-0187 has been newly started in Japan. This is a new compound with a planned indication of narcolepsy, and its profile is summarized on page 22 of the reference material. The development of DSP-1181 has been discontinued due to the failure to achieve the expected criterion in the Phase I study.

In the area of oncology, the interim analysis of the Phase III study of DSP-7888 for glioblastoma, which was being conducted in the U.S. and Japan, was discontinued because the final analysis showed that it was unlikely to significantly prolong OS, the primary endpoint of the study. In addition to the U.S., a Phase I study of DSP-5336 for hematological malignancies has been initiated in Japan.

In other areas, a Phase I study of KSP-1007 was newly initiated in the U.S. This drug is a new compound discovered through joint research with The Kitasato Institute, and its profile is summarized on page 23 of the reference material. The planned indications are complicated urinary tract infections and complicated intra-abdominal infections. The development of SMC-01, a type 2 diabetes management guidance application, was discontinued due to the failure to meet the primary endpoint of the Phase III study.



Please see page 16.

Regarding the product launch target, we have changed the launch target of ulotaront in the U.S. from FY2023 to FY2024. The results of the Phase III study of ulotaront for schizophrenia will shift from the first half of FY2022 to the second half of FY2022 due to COVID-19. As a result, the schedule has been revised to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in FY2023 and commercial launch in FY2024.

As for the Parkinson's disease cell therapy, the launch target has been changed from FY2023 to FY2024, following the completion in 2021 of the transplantation of the seventh and final patient in the investigator-initiated clinical study at Kyoto University.

This concludes the explanation.

Harada: Thank you very much, Mr. Kashima.

Now, Mr. Nomura would like to continue with a few words. Mr. Nomura, please.

Nomura: Thank you very much for taking time out of your busy schedules to participate in our conference call today.

Our company has today announced a revision to our financial results for FY2021. I expect that there will be many other questions from you and I would like to answer as many of your questions as I can.

Harada: Thank you very much, Mr. Nomura.

Question & Answer

Harada: I would now like to move on to the question-and-answer session.

Questioner 1: First, regarding LATUDA® in North America. What is your view for the third and fourth quarters? In the third quarter, the figure was JPY56.1 billion, and I thought it would not be so bad if I only looked at the third quarter figures. As the downward revision for the full year was quite large, it will not grow so much for the fourth quarter.

I think the average sales price will go down now because more people will be using Medicaid, but is it correct to understand that the fourth quarter will be so bad that the unit price will fall rather than the volume? I think the numbers in the third quarter weren't so bad, so could you tell us a little more about the third and fourth quarters?

Kashima:

First of all, in terms of the annual comparison between the previous fiscal year and the current fiscal year, the price and the volume were about half and half, respectively, which the actuals are lower than our expectations. In the third quarter, there were a lot of shipments in December, so we expect that there will be some inventory adjustments in the fourth quarter as a reaction to that, and we think that the annual forecast will be within this range.

Questioner 1: I understand. Thank you.

Secondly, in the North America segment, the ORGOVYX® and Others segment has been revised downward from JPY87.1 billion to JPY72.9 billion. Is it correct to say that the JPY11 billion in alliance revenue that was included in the initial forecast for the Others segment has been postponed to the next fiscal year because it has become difficult to form alliances this fiscal year?

Nomura:

We had been talking with various companies about alliances, including alliances for SEP-363856, SEP-4199, and two other products, so one of the things we did was to include a certain amount of consideration for alliances in our estimate. In addition, we originally planned to actively pursue alliances in our Mid-term Business Plan, so some of the considerations were factored in.

However, I would like to refrain from commenting on whether it has shifted or not, as I am not at liberty to do so now. But of course, we will continue to work on such partnership activities.

Questioner 1: I understand. If that is the case, although the strategy of the alliance remains unchanged, is it correct to understand that the specific figure of JPY11 billion has become difficult to factor in for this fiscal year, so it is no longer possible to give a specific figure, rather than saying that it will be moved to the next fiscal year or something like that?

Nomura: I think that would be a good way to understand it.

Questioner 1: I understand.

The third and final one. I think that the downward revision for ORGOVYX®, MYFEMBREE®, and GEMTESA® is probably about JPY3 billion. In terms of the progress before the third quarter, which ones are being lowered in particular, and when you look at them individually, what is your company's view of each?

Nomura: Since there are listed companies involved it is difficult for me to make any comments about them. Myovant Sciences has already held a press conference, or rather a telephone conference, so in that sense, I think you have a good understanding of the current situation, and I hope you can make assumptions based on the various information you have.

Questioner 1: I understand. I understand the actual results, but I was wondering how your company's forecast was doing in relation to the actual results. Are you saying that you can't tell us about that either?

Nomura: As mentioned, I can't say anything about that.

Questioner 1: I understand. Thank you. That's all.

Harada: Thank you very much.

Questioner 2: Thank you for the opportunity.

First, regarding the change in the U.S. launch target for ulotaront. I think you mentioned that the timing of the Phase III results is now expected to be in the second half of FY2022. I believe that this was designated as a breakthrough therapy, so based on the FDA's review period, if the results are to come out relatively early in the second half of FY2022, it could be released just in time to go on the market in FY2023. Is it correct to assume that the changes have already been made at this point for FY2024, and that the results are likely to come out relatively late in the second half of FY2022?

Kimura: This is Kimura.

We had very high expectations for this project, but due to the COVID-19, we had to change our projections as a result of a careful review of the current progress last fall.

We are currently explaining the second half of FY2022. I would like to refrain from commenting on further details today, as there are some uncertain factors. However, as you mentioned, this is breakthrough therapy, so we took into account the fact that the review period will be shorter than usual and made the change to submit an NDA in FY2023 and launch in the first half of FY2024 as I mentioned earlier.

Questioner 2: The launch will be in the first half of FY2024, right? Thank you.

Also, I would like to ask you again about your thoughts on the strategy for oncology. Phase III of DSP-7888, which had been under development, turned out to be a disappointment, and although there are not many of them at the moment, I think you continue to see that those that have made it to the later stages of development end up disappointing in the end. In light of the recent progress, I would like to ask again how you are planning to invest resources in the oncology area, which is currently only in the early stages.

Nomura: This is Nomura. Thank you.

The DSP-7888 did not work well for glioblastoma this time, so it was discontinued. However, we have not given up on the potential of DSP-7888, and although it is described here as a solid tumor, it is still in progress, and we are still expecting more from it.

Although the DSP-7888 study did not go well this time, of course we have collected data and blood samples from the patients, so we will analyze the data thoroughly to see what we can learn from it and how we can apply it to the other DSP-7888 study that is currently underway. That is what we will be thinking about.

As for the future of the oncology area, it is true that there are only early-stage compounds available now, as you mentioned. As I have said before, we will try this out on a small number of patients, and only if there is a good response we will proceed to the next stage. I would like to take a very slow approach.

Although it has not yet been put into clinical use, we have some attractive compound candidates in the research stage. In this sense, I believe that we still are well positioned to compete in the area of oncology.

However, in terms of resource allocation, since the pipeline itself is in its early stages, we will probably not be able to allocate such a large number of resources for the next few years.

Questioner 2: Thank you very much.

Lastly, DSP-0187, a drug for narcolepsy that is now in Phase I, is an orally administered orexin 2 receptor agonist, and it looks very similar to what Takeda Pharmaceutical is focusing on. Do you have any comments on what kind of differentiation you expect?

Kimura: Kimura will provide that answer.

I know that Takeda Pharmaceutical is putting a lot of effort into orexin receptor agonists. In fact, we had been conducting independent research, and we only became aware of it when Takeda Pharmaceutical 's patent was granted first.

As a result, we are proceeding with a compound that has a completely different backbone from the compound being developed by Takeda Pharmaceutical and as you know, Takeda Pharmaceutical's first compound was announced to be toxic to the liver. In this case, I think the profile will be completely different.

On the other hand, although I can't go into details today, we are thinking of moving forward with clinical development because we believe that we can differentiate our products in terms of their effect.

Questioner 2: Thank you very much. That's all.

Harada: Thank you very much.

Questioner 3: Thank you for taking my question. I would also like to hear about your thoughts.

You explained earlier that it was difficult to comment on the three products because of the situation with the other companies, but if the sales of the three products were to fall far short of your company's expectations, I think your company had originally assumed that the sales of these three new drugs would increase significantly in preparation for the LATUDA® patent cliff, and that this would be offset to some extent. If these three products fall far short of your expectations and LATUDA® patent cliff, is likely to grow considerably, will you be actively considering the acquisition of new products or M&As?

Nomura: Thank you for your question.

As to the earlier question, there was a downward revision of JPY3 billion with three products, but this is due to the fact that it was difficult to promote them sufficiently due to COVID-19. Access for sales reps was also very limited, especially for ORGOVYX®.

Also, MYFEMBREE® was launched in June, but the peak of COVID-19 came soon after, so sales reps were not able to promote it directly until the beginning of October, and their activities were very limited. I think that had a big impact.

Now that we are talking about the Omicron variant, I will mention that in the future we are also going to be relatively more active in the marketplace. I don't know how much the access of these sales reps at medical institutions will be improved, but I think it will be better than before.

In addition, I believe that the digital promotion skills using virtual meeting platforms are improving, so I believe that the various sales promotion issues related to COVID-19 will gradually be resolved.

In that sense, although there was a slight difference this fiscal year, we are hopeful that we will be able to draw a certain growth curve in the future. Therefore, at the moment, we are not looking to acquire new drugs or anything like that, but rather to focus on measures to firmly grow these three products.

Questioner 3: Alright. Thank you. I understand now.

Lastly, Other Regions, while you have revised upward the sales from JPY10.3 billion to JPY12. billion, you have revised downward your core segment operating profit from JPY4.1 billion to JPY2.9 billion. Thank you.

Kashima: Other Regions, page 10, right? The timing of the transfer of our subsidiary in Europe was originally planned to be a little earlier, but it was delayed a little, and the expenses incurred during that period were included, so the loss increased a little.

Questioner 3: I understand very well. Thank you. That's all from me.

Harada: Thank you very much.

Questioner 4: I didn't get a chance to participate at the beginning, so maybe you have already answered this question, but when Otsuka Holdings announced its downward revision last week, I think it mentioned in writing that R&D expenses had increased in relation to the four products in the alliance with your company. As I recall, you don't mention R&D expenses in this section, so it is a neutral factor for your company. In the fourth quarter, whether you use it that much or not, is this understanding, correct?

Kashima: Yes, I think that's a good understanding.

Questioner 4: I understand. So, this is a factor or a circumstance of Otsuka Pharmaceutical.

Another thing I would like to ask you is that last week, President Nomura, I think it was for the media, made a comment that after the LATUDA® patent cliff, they would get through it in a year and then make a rapid recovery. I don't know how accurate the numbers are, but I think that's what they said.

On the other hand, the timing of the downward revision seems to be very bad, and I wonder what kind of intentions led to that statement. Maybe it wasn't the President's main intention, was it? I would like to ask you about such things as well.

Nomura: This is Nomura. Thank you for your question.

I think what it said in the media was that the situation will be challenging in FY2023, but after that, the three products I mentioned earlier will grow, and we will be able to recover from the big drop of LATUDA®.

Therefore, I understand that I have explained the top line movements, and that the profit and loss will recover to a certain extent by, say, FY2025. I don't think there is any particular relevance between the downward revision of the business forecast that we announced today and the business results for FY2024 and beyond.

Questioner 4: I understand. I was just curious. Thank you very much.

Harada: Thank you very much.

Questioner 5:

I think you have a target of JPY60 billion for the next fiscal year and JPY120 billion for FY2025 in a revised Mid-term Business Plan. You've made some revisions this time, but there are some bumps in the road, and LATUDA® is down, but from a Mid-term Business Plan perspective, I'm not sure if you need to make any major changes there. Listening to you, I was thinking that it is not necessary at all, but what do you think about that?

Nomura: From a Mid-term Business Plan perspective, I think it is a difficult question to answer whether we need to revise the figures for FY2025 now.

We believe that our performance in FY2025 will be highly dependent on the growth of ORGOVYX®, MYFEMBREE®, and GEMTESA® which I mentioned earlier.

So, it depends on how these three products will grow in FY2022, FY2023, and FY2024. At this point, I'm not sure if we need to revise the figures that you mentioned earlier for FY2025.
I don't know whether we should call our new lifestyle the new “with coronavirus pandemic” or “after coronavirus pandemic”, but I believe that the key to our success lies in how much we can expand these three products in the situation of coronavirus pandemic.

Questioner 5: How about JPY60 billion for FY2022? It will be next year.

Nomura: As for FY2022, we are in the process of compiling the budget, so I would like to refrain from mentioning that.

Questioner 5: I understand.

Also, it's ulotaront. You've had a few delays, but the COVID-19 situation has almost run its course, and this is the final form of delay, or do you think there will be no more delays? Or is it possible that there are still many variables to be considered? I have heard the same thing before, but are you going to introduce the theme or content of the development of the next indications, including Otsuka Pharmaceutical, one by one yet? These two questions.

Kimura: I will provide an answer.

As for the impact of COVID-19, Japan is still not in the process of peaking, but, Europe, and the United States appear to be near the peak. On the other hand, in the global clinical studies, we have entered many patients in countries other than the U.S., and of course there are many countries where the situation is very bad.

On the other hand, as a result of careful examination based on the current situation, we have decided on the timing as mentioned earlier, so as far as we can predict, we are proceeding with the launch in the first half of FY2024 as I mentioned. We are hoping that the environment will improve so that we can proceed with the project on that schedule.

As for the second and third indications with Otsuka Pharmaceutical, they are also a specialized company, so they have already agreed on what indications would be best based on the same data. However, we are currently working on other measures to increase the value of the product and the details of the clinical study protocol. We hope to be able to introduce this information to you when we announce our next annual results.

Questioner 5: I see. So, you are likely to be able to introduce us to the option of an additional indication.

Kimura: Yes, that's right.

Questioner 5: I understand. Thank you. That's all.

Harada: Thank you very much.

Questioner 6: The first point is, I don't know if I'm hearing this wrong, but I was a little concerned about the fact that the share of GEMTESA®, even in January, the coverage rate has not changed that much in the places where they are prescribing. I thought the U.S. usually decides on a new formulary or something at the beginning of the year in January, but why is this supposed to go up over the course of the year? Is there anything you can explain about that?

At the same time, from the President's point of view, what do you think about GEMTESA®? I think it was quite difficult this time because of COVID-19 and so on, but I would like to know if there is any change in your expectations for GEMTESA®. This is the first point.

Nomura: Thank you for your question.

The insurance coverage is expected to increase to some extent by the end of this fiscal year, or the end of March, so we are not that worried about it, and the people who are working on this are specialists in this area, as you know, so I think they are making good progress.

As for GEMTESA®, our subsidiary Urovant Sciences sales reps and Sunovion Pharmaceuticals sales reps share the responsibility for promotion, and I think they are doing a very efficient job. GEMTESA® has a very powerful predecessor, but I think we have been able to differentiate ourselves in many ways, so we are confident that GEMTESA® will become a large-scale product as we had originally hoped, and that has not changed at all. Therefore, we will make every effort to grow this product well.

Questioner 6: Regarding the second point, Myovant Sciences has already made an announcement, and when I looked at the contents of their announcement, they disclosed quite a bit of detail about both ORGOVYX® and MYFEMBREE®. In particular, in the case of MYFEMBREE®, the sales are still small, but the share of prescriptions among new patients has increased to 45%, et cetera. Is there any problem in writing the same kind of information on your slide for something that has already been disclosed? I think it would probably be more friendly for everyone.

Nomura: Thank you very much.

I don't think it is a problem to include in our slides those that have already been published. If it is more convenient for you, we will consider the slide presentation in that direction.

Questioner 6: Yes, thank you. Understanding that these drugs are core to the business, it would be helpful to see more detail in this regard to assist with future understanding.

Nomura: Thank you very much.

We would like to put a lot of effort in this area, and it is absolutely true that we would like you to understand this as well, so we will think about how to put this on our slide and present it at the next opportunity. Thank you.

Questioner 6: Thank you very much.

Harada: Thank you very much.

Now, I would like to conclude the question-and-answer session. Thank you for your questions.

This concludes the conference call. Thank you very much for your time today.

[END]