Summary of Investors Meeting for Q2 FY2021

[Date]	October 28, 2021 10:30 - 11:33 (Total: 63 minutes, Presentation: 18 minutes, Q&A: 45 minutes)	
[Venue]	Live stream and conference call	
[Number of Speakers]	3	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Executive Vice President, Chief Scientific Officer
	Miwako Harada	Senior Director, Corporate Communications

Disclaimer:
This is a summary of the Q2 FY2021 call and clarifies certain information provided. Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group holds approximately 54% 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: Now it is time to begin Sumitomo Dainippon Pharma Co., Ltd.'s financial results announcement for the second quarter of FY2021. Thank you very much for taking time out of your busy schedule to join us today. Today, we would like to proceed via live streaming and conference call.

Here are a few things to keep in mind before we start. Today's presentation will be based on the presentation materials posted on our website. The live video is not synchronized with the materials, so please proceed through the pages on your own.

After the main presentation, we will have time for a question and answer session, so please ask any questions you may have via the phone line. Please note that we may not be able to answer all questions due to time constraints.

This meeting will also be recorded for later distribution on the website. Please note this in advance.

First, I would like to introduce today's speakers from the Company today. Mr. Nomura, President and CEO; Dr. Kimura, Representative Director, Executive Vice President, Chief Scientific Officer; and myself - Harada, Senior Director, Corporate Communications.

Now, Mr. Nomura would like to explain the financial results for the second quarter of FY2021.

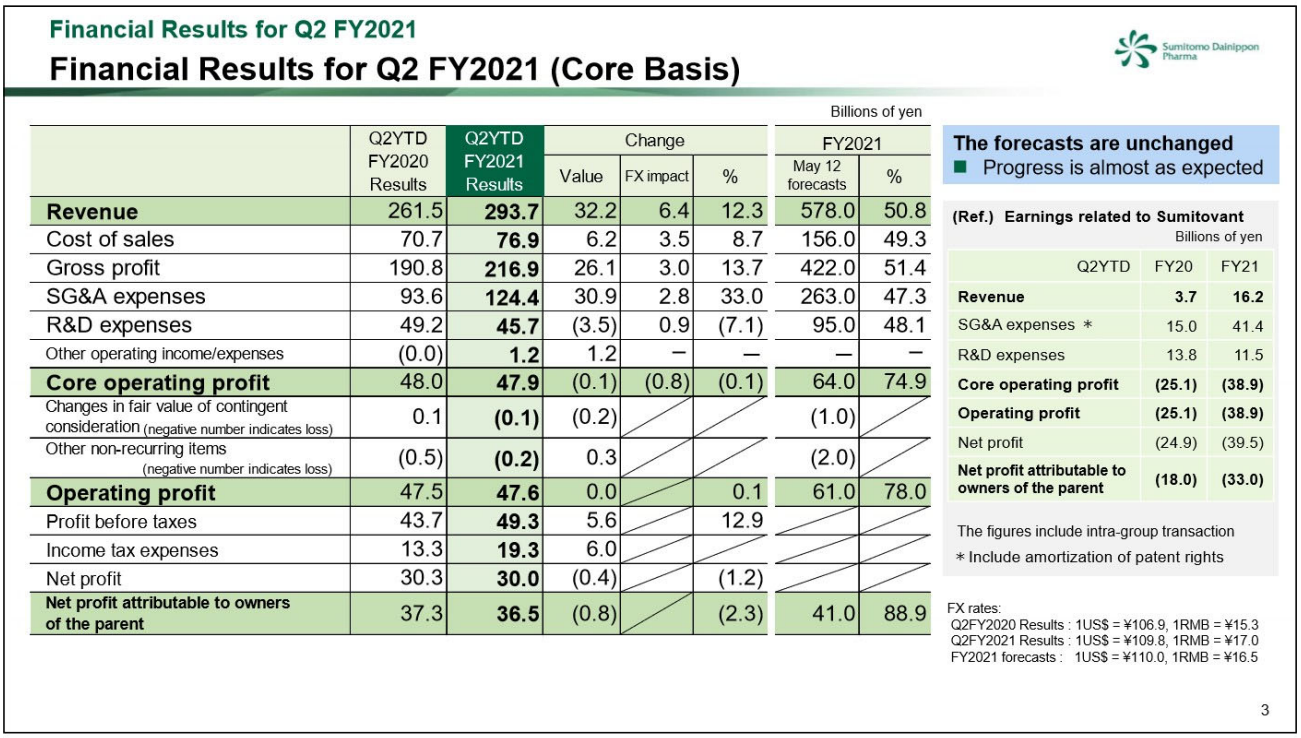
Mr. Nomura, please go ahead.

Nomura: Thank you, Harada-san. Good morning. Thank you very much for taking time out of your busy schedule to participate in our financial results announcement for the second quarter.

I would also like to take this opportunity to express my sincere gratitude for your continued interest in our Company's management and your valuable feedback.

Our stock price has been moving quite a bit since this morning. I think it had to do with the closing of accounts, but we will take this move seriously, analyze it carefully, and utilize it in our future management.

Now, I'd like to get right to the point.



Financial Results for Q2 FY2021

Financial Results for Q2 FY2021 (Core Basis)

Billions of yen

	Q2YTD FY2020 Results	Q2YTD FY2021 Results	Change			FY2021	
			Value	FX impact	%	May 12 forecasts	%
Revenue	261.5	**293.7**	32.2	6.4	12.3	578.0	50.8
Cost of sales	70.7	**76.9**	6.2	3.5	8.7	156.0	49.3
Gross profit	190.8	**216.9**	26.1	3.0	13.7	422.0	51.4
SG&A expenses	93.6	**124.4**	30.9	2.8	33.0	263.0	47.3
R&D expenses	49.2	**45.7**	(3.5)	0.9	(7.1)	95.0	48.1
Other operating income/expenses	(0.0)	**1.2**	1.2	–	–	–	–
Core operating profit	48.0	**47.9**	(0.1)	(0.8)	(0.1)	64.0	74.9
Changes in fair value of contingent consideration (negative number indicates loss)	0.1	**(0.1)**	(0.2)			(1.0)	
Other non-recurring items (negative number indicates loss)	(0.5)	**(0.2)**	0.3			(2.0)	
Operating profit	47.5	**47.6**	0.0		0.1	61.0	78.0
Profit before taxes	43.7	**49.3**	5.6		12.9		
Income tax expenses	13.3	**19.3**	6.0				
Net profit	30.3	**30.0**	(0.4)		(1.2)		
Net profit attributable to owners of the parent	37.3	**36.5**	(0.8)		(2.3)	41.0	88.9

The forecasts are unchanged
■ Progress is almost as expected

(Ref.) Earnings related to Sumitovant

Billions of yen

Q2YTD	FY20	FY21
Revenue	**3.7**	**16.2**
SG&A expenses *	15.0	41.4
R&D expenses	13.8	11.5
Core operating profit	**(25.1)**	**(38.9)**
Operating profit	**(25.1)**	**(38.9)**
Net profit	(24.9)	(39.5)
Net profit attributable to owners of the parent	**(18.0)**	**(33.0)**

The figures include intra-group transaction
* Include amortization of patent rights

FX rates:
Q2FY2020 Results : 1US$ = ¥106.9, 1RMB = ¥15.3
Q2FY2021 Results : 1US$ = ¥109.8, 1RMB = ¥17.0
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

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Page 3. The Company's revenue was JPY293.7 billion, an increase of JPY32.2 billion compared to the same period last year. As we have already announced, we have received an upfront payment of USD270 million from Otsuka Pharmaceutical Co., Ltd. for joint development and commercialization, which has a significant impact.

The cost of sales has increased slightly, but this is due to the fact that sales of Sumitovant group products have increased, and the realized portion of LATUDA®'s unrealized profit has increased because of the depreciation of the yen. As a result, gross profit increased by JPY26.1 billion.

On the other hand, SG&A expenses increased by JPY30.9 billion. As you can see later in the segment information, SG&A expenses for Sumitovant increased in the US, as you can see on the right. This is due to the fact that we have actually started sales activities such as with Myovant and Urovant, so these expenses have increased.

In the same period of the previous fiscal year, due to the impact of the COVID-19 pandemic, we were not able to spend as much on normal business activities, but it has returned to the original level to some extent.

R&D expenses have decreased by JPY3.5 billion, but this is because the development of napabucasin, alvocidib, and relugolix has come to an end. Accordingly, as a whole, it is in the direction of decrease. As a result, core operating profit was JPY47.9 billion, which is almost the same as the same period last year.

In addition, there were no major changes in fair value of contingent consideration and other non-recurring items, so operating profit was JPY47.6 billion, which is also the same as the same period last year.

Profit before taxes increased by JPY5.6 billion, but this was due to a difference of about JPY6 billion between the top and bottom in financial expenses and income, as foreign exchange losses in the same period of the previous year were offset by foreign exchange gains in the current period.

In addition, income tax expenses have increased because, while profits have increased for our Japanese corporation, losses have increased in areas such as Sumitovant, where tax effects cannot be obtained. Thus, only the tax has slightly increased.

Finally, profit attributable to owners of the parent was JPY36.5 billion, down about JPY800 million year over year.

As a result, we are not going to revise our forecast at this time.

Financial Results for Q2 FY2021

Revenue of Major Products in Japan

Sumitomo Dainippon Pharma

Billions of yen

	Q2 YTD FY2020 Results	Q2 YTD FY2021 Results	Change		FY2021	
			Value	%	May 12 forecasts	%
Equa®/EquMet®	20.4	**19.3**	(1.2)	(5.7)	37.4	51.5
Trulicity® *	16.8	**17.2**	0.4	2.3	38.2	45.0
TRERIEF®	8.3	**8.4**	0.2	1.9	17.9	47.1
REPLAGAL®	6.9	**7.1**	0.2	2.9	13.8	51.5
METGLUCO®	4.7	**4.1**	(0.6)	(11.8)	6.9	60.0
LATUDA®	0.9	**3.0**	2.1	243.6	6.7	44.9
LONASEN® Tape	0.6	**1.0**	0.4	71.9	2.5	38.2
AMLODIN®	3.3	**2.9**	(0.4)	(13.3)	5.0	57.8
AG products	3.8	**4.8**	1.1	28.3	10.1	47.7
Others	11.7	**8.8**	(2.9)	(25.1)	11.5	76.4
Total	77.3	**76.6**	(0.8)	(1.0)	150.0	51.1

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

- Progress is almost as expected in the segment total
- Decrease in Equa®/Eqmet® is attributed to NHI price revision
- LATUDA® showing steady growth
- Others include TWYMEEG® launched on September 16
- NHI price revision affected ¥3.5B on Japan segment total

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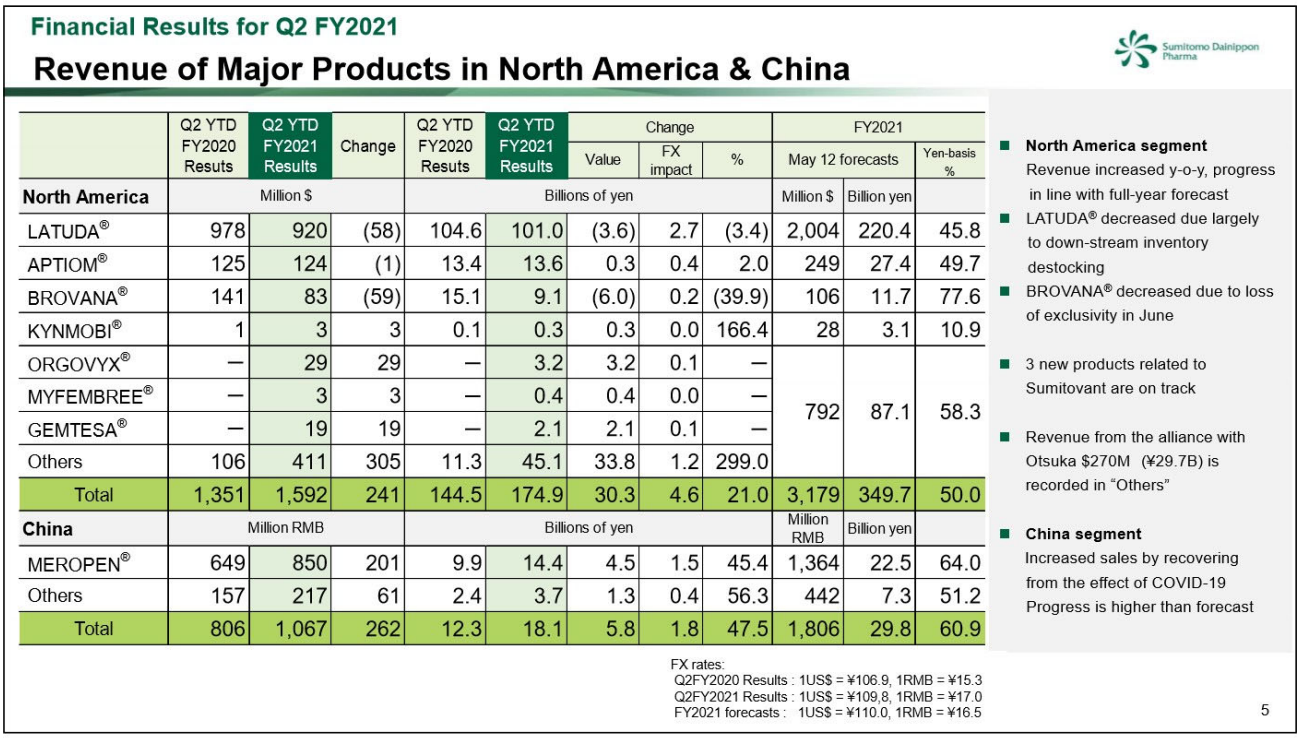
This is the revenue in Japan, and it is 51.1% of the forecast, which is almost in line with the progress.

The NHI drug price revision recently had a negative impact of about JPY3.5 billion, so I think we did very well in terms of volume.

There has been an increase in the number of Equa®/EquMet® and Trulicity®. Although Equa®/EquMet® is negative in terms of monetary amount, the volume is increasing. LATUDA® also increased.

In addition, although the progress of LONASEN® Tape has been a little slow, it has increased year over year.

Overall, there was a year over year decrease of about JPY800 million.



Financial Results for Q2 FY2021

Revenue of Major Products in North America & China

Sumitomo Dainippon Pharma

	Q2 YTD FY2020 Resuts	Q2 YTD FY2021 Results	Change	Q2 YTD FY2020 Resuts	Q2 YTD FY2021 Results	Change			FY2021		
						Value	FX impact	%	May 12 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billion yen	
LATUDA®	978	920	(58)	104.6	101.0	(3.6)	2.7	(3.4)	2,004	220.4	45.8
APTIOM®	125	124	(1)	13.4	13.6	0.3	0.4	2.0	249	27.4	49.7
BROVANA®	141	83	(59)	15.1	9.1	(6.0)	0.2	(39.9)	106	11.7	77.6
KYNMOBI®	1	3	3	0.1	0.3	0.3	0.0	166.4	28	3.1	10.9
ORGOVYX®	–	29	29	–	3.2	3.2	0.1	–	792	87.1	58.3
MYFEMBREE®	–	3	3	–	0.4	0.4	0.0	–			
GEMTESA®	–	19	19	–	2.1	2.1	0.1	–			
Others	106	411	305	11.3	45.1	33.8	1.2	299.0			
Total	1,351	1,592	241	144.5	174.9	30.3	4.6	21.0	3,179	349.7	50.0
China	Million RMB			Billions of yen					Million RMB	Billion yen	
MEROPEN®	649	850	201	9.9	14.4	4.5	1.5	45.4	1,364	22.5	64.0
Others	157	217	61	2.4	3.7	1.3	0.4	56.3	442	7.3	51.2
Total	806	1,067	262	12.3	18.1	5.8	1.8	47.5	1,806	29.8	60.9

FX rates:
Q2FY2020 Results : 1US$ = ¥106.9, 1RMB = ¥15.3
Q2FY2021 Results : 1US$ = ¥109.8, 1RMB = ¥17.0
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

- **North America segment**
  Revenue increased y-o-y, progress in line with full-year forecast
- LATUDA® decreased due largely to down-stream inventory destocking
- BROVANA® decreased due to loss of exclusivity in June
- 3 new products related to Sumitovant are on track
- Revenue from the alliance with Otsuka $270M (¥29.7B) 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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In the North America segment, you can see the unit of billions of yen in the middle.

LATUDA® was JPY101 billion, a year over year decrease of JPY3.6 billion. As you can see on the right, we are a little behind the forecast, at 45.8%. As you can see the comments on the side of this page, there was an increase in distribution inventory last fiscal year.

In the last fiscal year, due to the impact of COVID-19, there was an increase in distribution stock due to 90-day prescriptions, etc., and this had an impact on the adjustment.

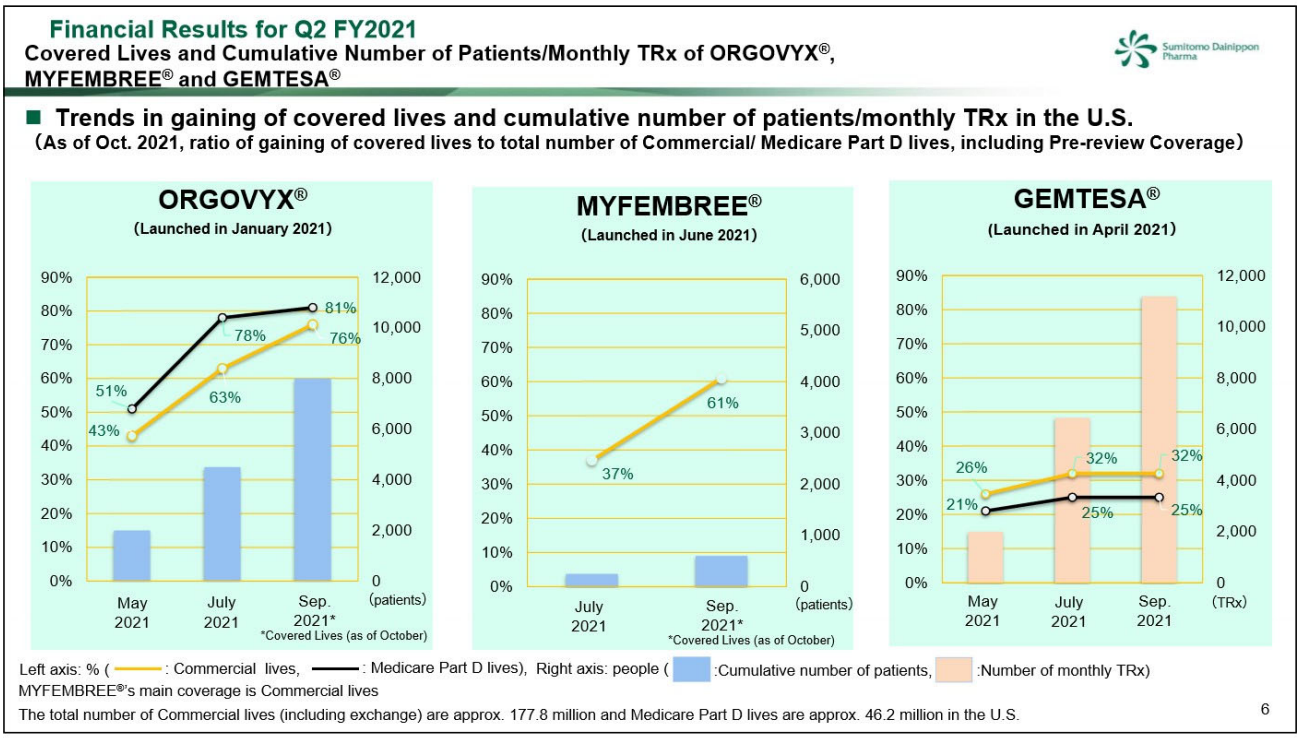
In terms of prescriptions, there have been no major changes, which is in line with our expectations.

As for BROVANA®, the patent has expired, so there was a decrease compared to the previous year.

In the Sumitovant subsidiaries, ORGOVYX® is JPY3.2 billion, MYFEMBREE® is JPY400 million, and GEMTESA® is JPY2.1 billion. As a whole, it was as expected, although I have the impression that MYFEMBREE® was a little smaller than expected.

As for others, it is JPY45.1 billion, a year over year increase of JPY33.8 billion. This includes the upfront payment from Otsuka Pharmaceutical, the revenue recognition from Pfizer Inc.'s partnership, and the revenue from Gedeon Richter Plc.

In the China segment, there was a year over year increase of JPY5.8 billion. Also, compared to the forecast, it is about 61%. It has increased from the previous year, but if you look at the same period two years ago, it is about JPY14 billion, so it is also increasing compared to that. This means that there is still a lot of room for growth for MEROPEN®.



This is just for your reference, showing the current insurance coverage for ORGOVYX®, MYFEMBREE®, and GEMTESA®, and the light blue bar graphs show the cumulative number of patients. Then, GEMTESA® shows the number of prescriptions.

In terms of ORGOVYX®, Medicare Part D coverage is at 81%, and commercial coverage is at 76% as of October.

As for MYFEMBREE®, it is 61%. Until September, we had roughly 600 patients, which is a little less than we expected. The product was launched in June, and after that, it was difficult for MRs to visit the market in person due to the COVID-19-related issues.

I think it was around September 23 when the in-person detailing actually resumed. In that sense, I think it was difficult to provide information on new products.

I also heard that gynecology was much more restrained in terms of consultations than other medical areas during COVID-19.

The first thing to do is to familiarize people with this new medicine. In order for the doctors to get to know it better, there was also a process of having them experience and confirm the effectiveness of our free program. So, in that sense, I feel that it is a little low as a start.

As for GEMTESA®, prescriptions are growing steadily. However, on the other hand, if you look at this, you will see that insurance coverage may not have grown much. This is something that we have been talking about with payers, and we will put it on the formulary when the formulary is reviewed by the other side.

I understand that it is not so different from the base of the formulary when mirabegron was launched.

Financial Results for Q2 FY2021

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q2 YTD FY2021 Results	Revenue (Sales to customers)	76.6	174.9	18.1	4.6	274.2	19.6	293.7
	Cost of sales	41.3	15.2	3.1	2.2	61.8	15.1	76.9
	Gross profit	35.3	159.6	15.0	2.4	212.4	4.5	216.9
	SG&A expenses	25.5	89.4	5.4	1.5	121.9	2.6	124.4
	Core segment profit	9.8	70.2	9.6	0.9	90.5	1.9	92.4
	R&D expenses					45.3	0.4	45.7
	Core operating profit					46.4	1.5	47.9
Q2 YTD FY2020 Results	Revenue (Sales to customers)	77.3	144.5	12.3	9.3	243.5	18.0	261.5
	Cost of sales	40.2	11.5	2.2	3.2	57.1	13.6	70.7
	Gross profit	37.2	133.0	10.1	6.2	186.4	4.4	190.8
	SG&A expenses	23.8	62.2	3.8	1.3	91.1	2.5	93.6
	Core segment profit	13.3	70.8	6.3	4.9	95.3	1.9	97.2
	R&D expenses					48.8	0.4	49.2
	Core operating profit					46.5	1.5	48.0
Change	Revenue (Sales to customers)	(0.8)	30.3	5.8	(4.8)	30.7	1.6	32.2
	SG&A expenses	1.7	27.2	1.6	0.3	30.8	0.1	30.9
	Core segment profit	(3.5)	(0.6)	3.3	(4.0)	(4.8)	0.0	(4.8)
	R&D expenses					(3.5)	0.0	(3.5)
	Core operating profit					(0.1)	0.0	(0.1)

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

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This is a breakdown by segment.

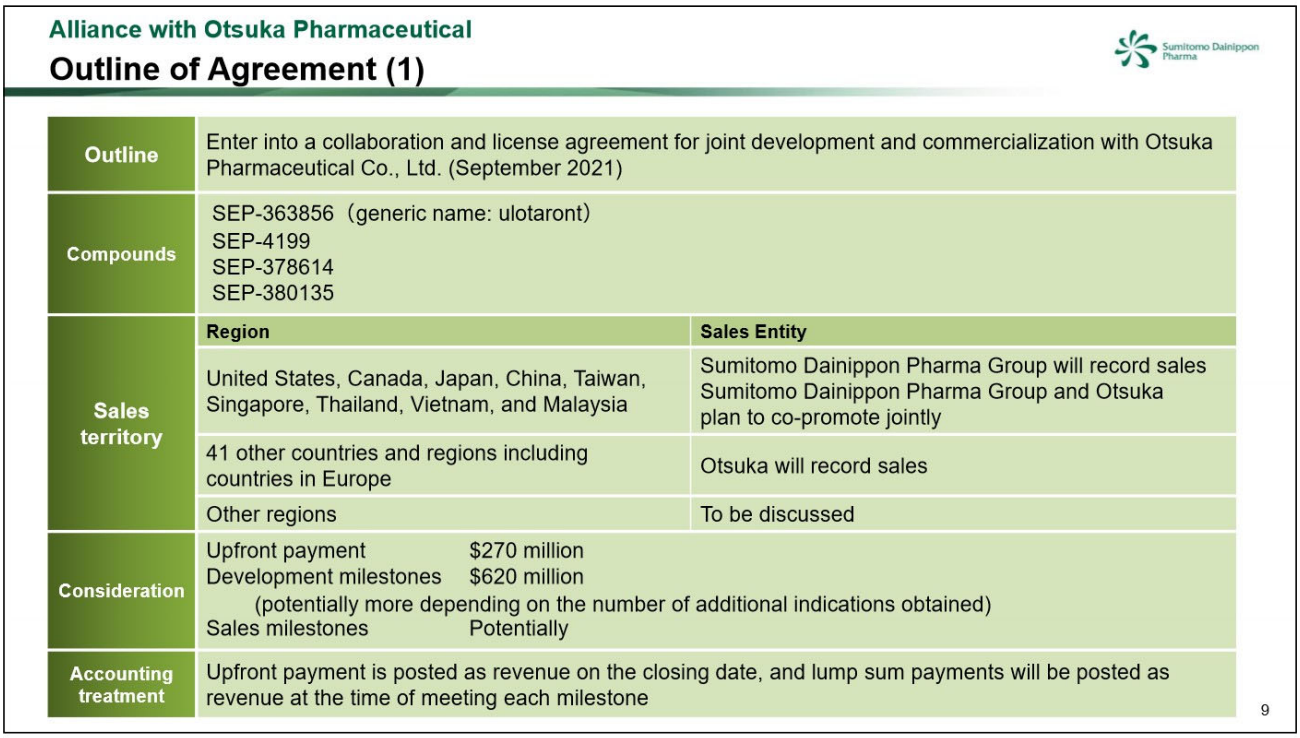
If you look at the increase/decrease column at the bottom of the page, you can see that Japan was affected by the NHI price revision.

We were unable to conduct sales activities in some areas due to COVID-19 during the same period last year.

In North America, there were some temporary gains, but expenses also increased, so there was a decrease of about JPY600 million.

Profit in China increased by JPY3.3 billion because of the increase in revenue.

Other Regions had a negative impact this time due to a temporary and intensive shipment in the same period last year.



Alliance with Otsuka Pharmaceutical

Outline of Agreement (1)

Outline	Enter into a collaboration and license agreement for joint development and commercialization with Otsuka Pharmaceutical Co., Ltd. (September 2021)	
Compounds	SEP-363856 (generic name: ulotaront) SEP-4199 SEP-378614 SEP-380135	
Sales territory	**Region**	**Sales Entity**
	United States, Canada, Japan, China, Taiwan, Singapore, Thailand, Vietnam, and Malaysia	Sumitomo Dainippon Pharma Group will record sales Sumitomo Dainippon Pharma Group and Otsuka plan to co-promote jointly
	41 other countries and regions including countries in Europe	Otsuka will record sales
	Other regions	To be discussed
Consideration	Upfront payment $270 million Development milestones $620 million (potentially more depending on the number of additional indications obtained) Sales milestones Potentially	
Accounting treatment	Upfront payment is posted as revenue on the closing date, and lump sum payments will be posted as revenue at the time of meeting each milestone	

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Regarding the alliance with Otsuka Pharmaceutical, when we reviewed our Mid-term Business Plan 2022 in May, I think we mentioned that we would reduce development risks and development cost share through the alliance.

One of the first projects is a partnership with Otsuka Pharmaceutical.

I said, around May, that the contract would be signed immediately, but it took some time, and we were able to finalize it by the end of the second quarter.

By doing so, we will be able to develop additional indications in parallel, which we would not be able to do independently.

We believe that this will generate greater synergy than, for example, developing ulotaront (SEP-363856) independently.

In that sense, I think this partnership will be very meaningful for us.

Alliance with Otsuka Pharmaceutical

Outline of Agreement (2)

Sumitomo Dainippon Pharma

Worldwide Joint Development for Four Candidate Compounds in Psychiatry & Neurology Area

Sumitomo Dainippon Pharma

sunovion

Otsuka

- The Joint Development Committee consisting of the three parties decides on the strategy, direction and roles of joint development
- Responsibility for conducting clinical studies will be decided for each indication

Compounds	Proposed indication	Development status	Future plans
ulotaront (SEP-363856)	Schizophrenia	U.S.: Phase 3 studies in progress Japan, China: Phase 2/3 study in progress	U.S.: Expecting topline results of Phase 3 studies in 2022 Aim to launch in FY2023 Japan, Asia: Aim to launch in the second half of the 2020s
	The second and third indications	-	Under consideration including conducting studies for the second and third indications in parallel
SEP-4199	Bipolar I depression	U.S.: Started Phase 3 study Japan: Preparing to join this Phase 3 study	U.S., Japan: Aim to launch in the second half of the 2020s
SEP-378614	To be determined	U.S.: Phase 1 study in progress	Under consideration
SEP-380135	To be determined	U.S.: Phase 1 study in progress	Under consideration

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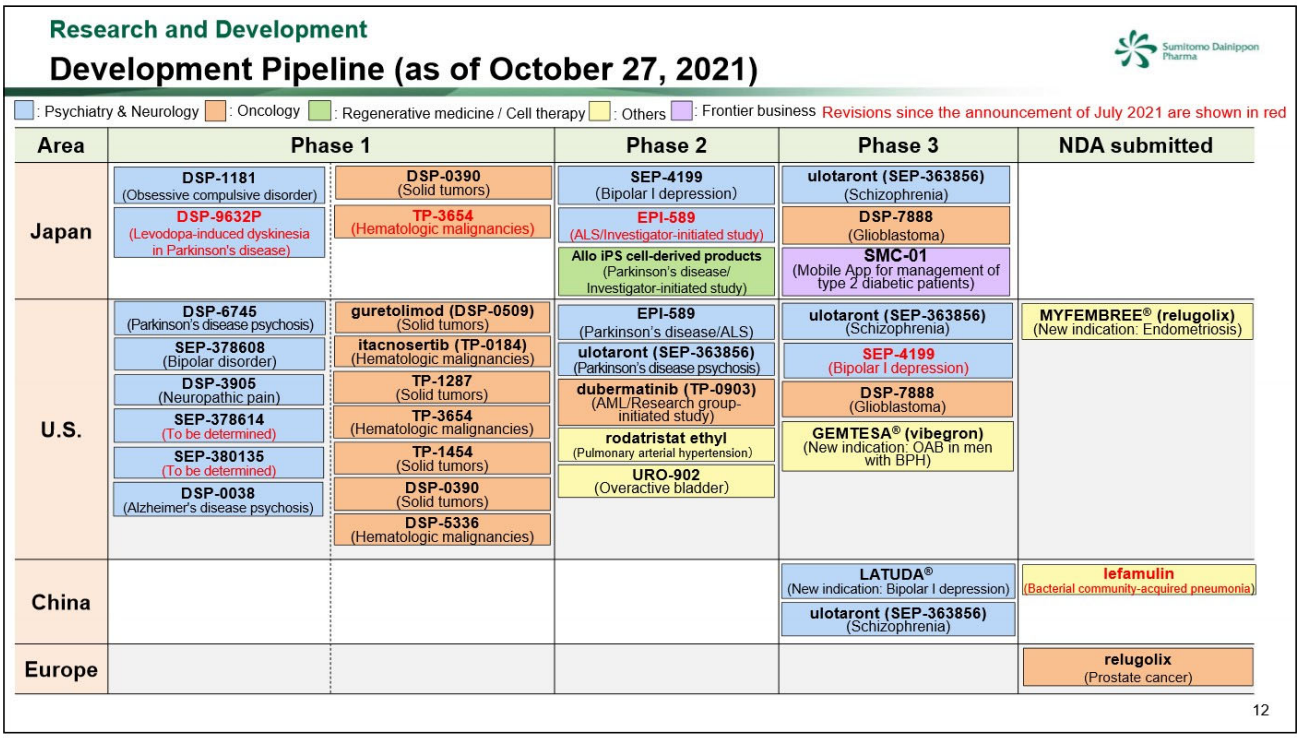
Since we will collaborate on joint development, we will establish the Joint Development Committee and decide who will be in charge of what indications for each compound, and how we will proceed.

The most urgent issue is to decide what to do for the second indication or third indication of ulotaront (SEP-363856).



As for the status of research and development, the areas in red are new additions.

Indications for two compounds in Phase 1 in the US that are the subject of the collaboration with Otsuka Pharmaceutical are yet to be determined.

Since both companies will decide on the indications, after consulting with each other, we have left them to be determined.

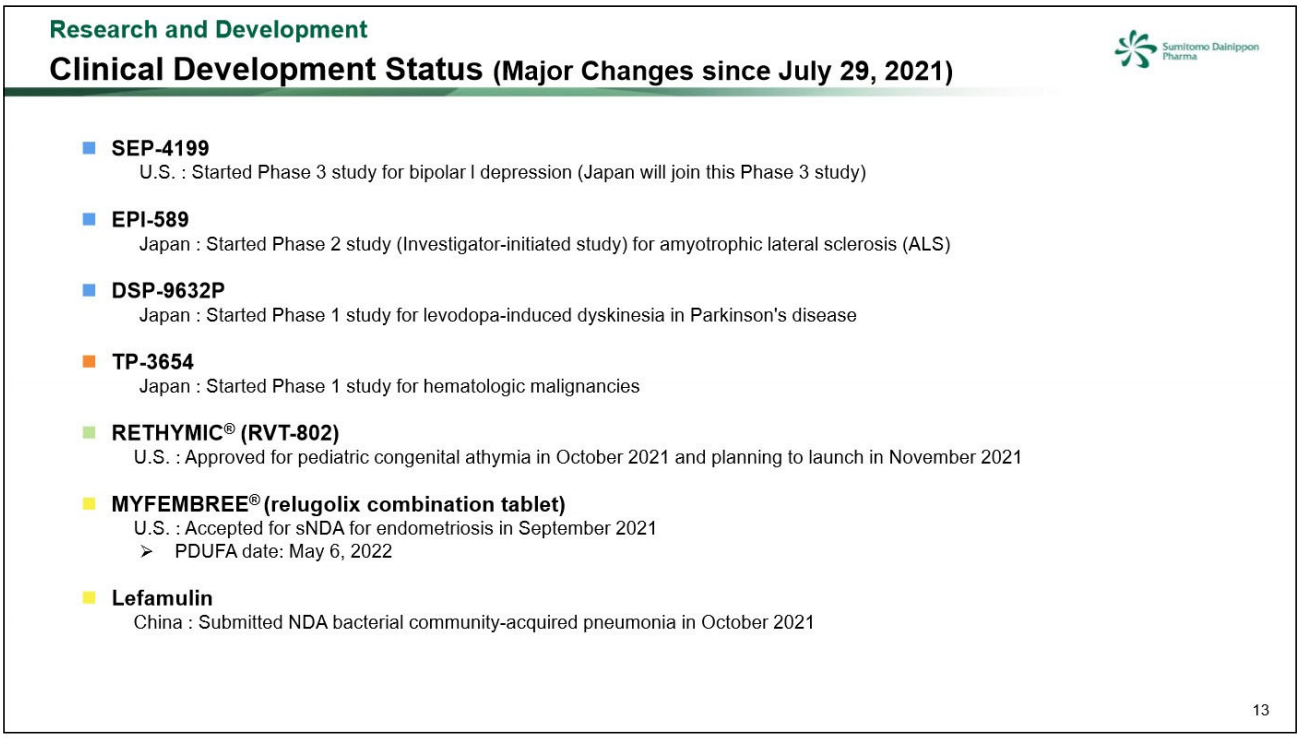
In Japan, we have the DSP-9632P, which is newly in Phase 1. This can be found in the reference section of the document, so please take a look.

As for the oncology area, TP-3654 in Japan is now in Phase 1.

EPI-589 in Phase 2 in Japan has started investigator-initiated study.

SEP-4199 in Phase 3 in the US shows that the phase of development has moved up.

In China, we have submitted an application for lefamulin, which is a compound that we acquired from Sinovant, and it is listed in the application section.



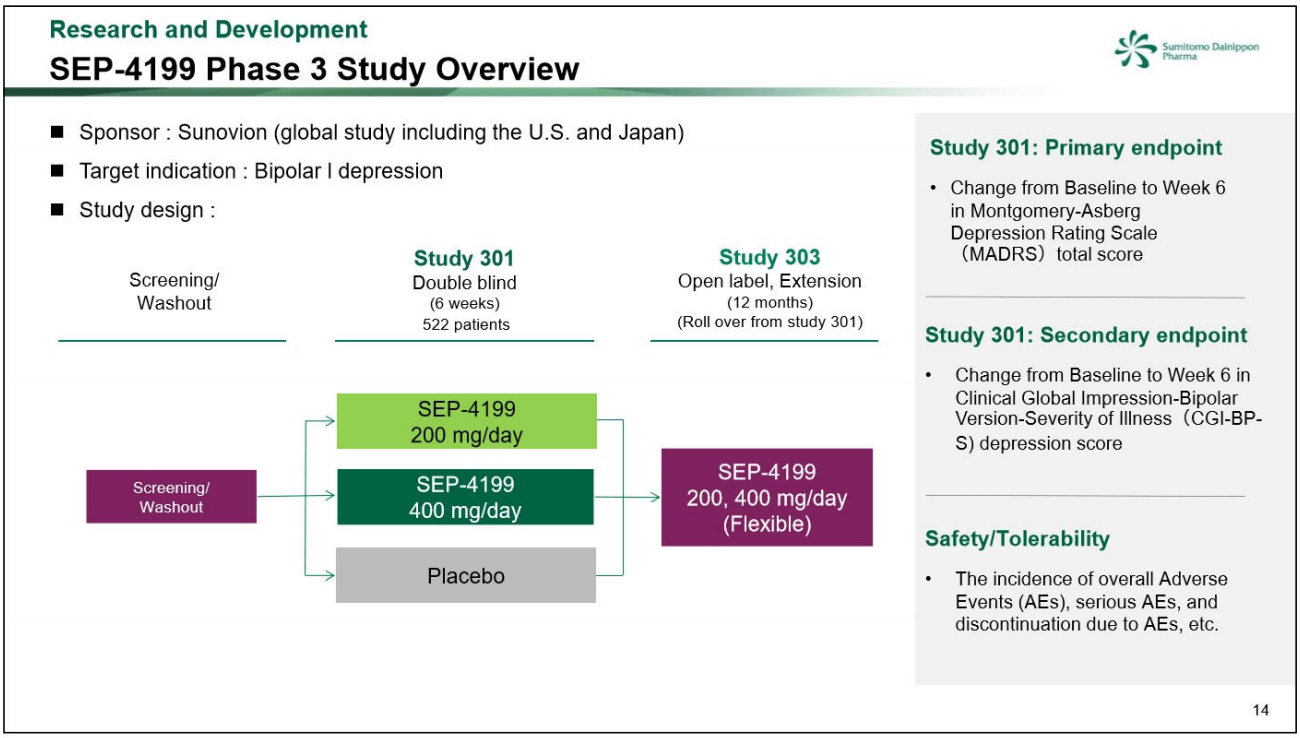
This is the description of what you have seen in the table.

RETHYMIC®, which is the third item from the bottom, is a one-time tissue-based regenerative therapy indicated for immune reconstitution in pediatric patients with congenital athymia in the US.

For every four million babies born, 17 to 24 will have congenital athymia.

In the US, newborns are screened, and patients with congenital athymia are quickly identified. The process is to have these patients operated on at Duke University.

It is engineered human thymus tissue for transplantation that can regenerate the thymic function children with this condition are missing.



This is SEP-4199 Phase 3study overview.

As you may remember, in Phase 2, there was a high placebo effect, and the results were not statistically significant, but the improvement trend was very good. So, we decided to start Phase 3 study, which is also part of the co-development program with Otsuka Pharmaceutical.

In Phase 3, we will do everything we can to prevent placebo effects from occurring.

The following is reference information, which I hope you will take a look at when you have time.

That is all I have to say.

I would like to use the rest of our time for Q&A.

Thank you very much for your kind attention.

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: My first question is about GEMTESA® on page 6. I think the progress of coverage is still a little slower than expected. I think there is an obvious differentiation between vibegron and mirabegron, such as that vibegron has fewer side effects of hypertension, better sharpness since the label states that it is effective in the second week, and no restriction of concomitant use with CYP2D6 inhibitors.

Nevertheless, it has only 30% coverage. The President Mr. Nomura said that it was compared with the progress at the time of the launch of mirabegron, but the disease, called OAB itself, is not so much recognized. So, I think it is significantly different from the current situation.

Certainly, I think there is a timing for it to be mentioned in the formulary, but even so, since progress has been slow, is there anything that was unexpected? For example, could you comment on what is inhibiting mirabegron's gross to net being much lower than expected?

Nomura: Thank you very much for your question. We also wonder why it is so low when we put these three side by side. So, Jim Robinson, who is in charge of Urovant, who used to work for mirabegron, told me that there is no delay or obstacle, but that this is the current coverage as planned.

So, in his opinion, we should communicate well with payers and make changes according to the timing of payer's review of the formulary.

This is how it is now, but I am not too worried about this kind of coverage at this point in time, because he has already said that the coverage will increase during the fiscal year.

Questioner 1: Plan is changed, and that the coverage and formulary are to be determined in January, is there a possibility that the coverage ratio will increase drastically in the period from October to December, or from January to March?

Nomura: Thank you very much. I don't know if it will go up significantly, but my understanding is that it will be much higher than at present. I regret that I cannot give you a figure, but I understand that it will increase.

Questioner 1: I understand. My second question is about the SEP-4199, which I've asked you about before. On July 7, 2020, the data of the results of the Phase 2 study were already released, and the change in MADRS score after 6 weeks of placebo was 16.2. Whether it was 200 mg or 100 mg, placebo was 16.2 points less.

The amount of change in MADRS score after six weeks, which is written on the LATUDA® label, is 15.4. In short, placebo was as effective as the effects of LATUDA® in the past. I see this as being the biggest problem with SEP-4199.

When I asked you last time, you mentioned that the problem is professional patients who walk through clinical studies. The design of the Phase 3 study is disclosed on slide 14. I would like to ask you to tell us how you are addressing this professional patient issue in this study.

Kimura: As to your question, in conducting the clinical study of SEP-4199, it is very important to have patients who may respond to the drug participate.

In the diagram on page 14, there is a purple box on the far left that says Screening/Washout. In particular, in the screening, we have been analyzing the data to see what kind of trend is seen in professional patients who are not responding well, or who have a placebo response, and we have found that there is a certain trend.

By taking advantage of this, we are able to select patients who will respond well to the drug in the normal screening process, which is the process of determining which patients can enter the clinical study.

I'll refrain from getting into specifics about what we are actually focusing on, as that would be considered know-how.

Questioner 1: As a supplementary question, does professional patient mean, in essence, a person who deliberately participates in various multiple clinical studies and doesn't seem to be taking much medication?

Also, Sequential Parallel Comparison Design is being pushed quite a bit by Dr. Maurizio Fava, but the FDA is still skeptical. Can we assume that you don't think much about exclusion or excluding people who have a placebo response in that way?

Kimura: As you mentioned, one way to think of it is to watch the patients for a while and exclude those who have had a placebo response. But in our case, we believe that we can exclude them by looking at the information of the patients.

In the US, patients are compensated for participating in clinical studies, so whether they take the medication or not, patients who are intended to participate in clinical studies are scored on their answers to various questions and responses to doctors, especially in the case of mental illness.

This is the reason why there are some clinical study subjects who do not reflect objective data.

Questioner 1: So, you don't think much about Sequential Parallel Comparison Design?

Kimura: We are thinking about it in various ways. But in this clinical study, as written here, screening will be done based on prior information.

Washout means to stop taking medication for a period of time to eliminate the effects of the various medications they have been taking.

Questioner 1: I understand. Lastly, the clinical trials.gov Phase 3 study of ulotaront (SEP-363856), which was scheduled to be completed this year, has been postponed until next year or later due to COVID-19.

Since the product will be launched in FY2023, the long-term safety study will be completed at the end of 2022. Is there any change to this?

Kimura: The whole thing is indeed a little behind schedule. Although we are several months behind, we have not moved the approval schedule as of yet. We are aiming for FY2023.

Questioner 1: I apologize for my long question, but is there any change in the ELEVATE 2 study of rodatristat ethyl, which is scheduled to be completed in early 2023? I'm personally looking forward to this.

Kimura: With regard to rodatristat ethyl by Sumitovant, there has been a slight delay in patient enrollment, and we are currently working to speed up the enrollment process. Therefore, looking at the situation, we may have to revise the end schedule of the clinical study.

At the moment, we have not yet sorted out what exactly we will do.

Questioner 1: I understand. Thank you very much.

Questioner 2: Thank you for your explanation. I have a few questions for you.

The first one is about revenue of LATUDA® in North America. According to your explanation three months ago, there were a lot of shipments by the end of December last year, and there was an inventory adjustment, which was completed by May, and the number of prescriptions has been returning since June. But I think that revenue in the period from July to September also decreased year over year.

Roughly speaking, last year, pharmacies, etc. had quite a large inventory level due to the COVID-19 situation. This year, the inventory level has returned to normal, but the revenue of LATUDA® were quite large last year. So as a result, compared to last year, it decreased. Is this correct?

Also, your progress to the full year forecast is now a little lower, but if I understand it this way, I think there is a downside risk for the entire year. What are your thoughts on this?

Nomura: Thank you very much for your question. As for inventory adjustments, as I mentioned three months ago, wholesalers' inventories have been adjusted to some extent, but there was still quite a bit of distribution inventory, and I think the effects of this continued until the second quarter.

I think we used to get a lot of questions in relation to COVID-19, regarding whether or not there would be an impact on people losing their jobs and going from Commercial to Medicaid. Indeed, if you look at the percentage of Medicaid in about February 2020, and the percentage of Medicaid in about March of this year, there is a slight increase.

However, if we look at September, we can see that the situation has almost returned to normal, which means that there is not much impact on that side. We think that the adjustment of distribution inventory has been delayed a little and it entered the second quarter.

As for what will happen in the future, I think the level of stock maintained by wholesalers and pharmacies will also have an impact on future sales. Therefore, we are not optimistic that LATUDA®'s revenue will achieve all of the forecasted amount, and we think there is some risk in that area.

However, we have talked with the sales team in the US, and they are determined to do their best to bring us as close to our target as possible.

Questioner 2: I understand very well. Thank you very much. Another thing is that the sales of MYFEMBREE® are still slow. At the presentation by Myovant, they said that rather than competing with the leading product of AbbVie, they would rather expand this market together than compete with them by raising awareness of GnRH antagonist.

How do you and Myovant plan to increase the awareness of this class and expand the market? Are there any prospects for a rapid increase in sales for the second half although sales in the first half were still weak?

Nomura: Thank you very much for your question. This class, or rather items with this mechanism of action, is a situation that our product has entered where only a product of AbbVie's was sold so far. In this sense, the conventional treatment policy of doctors is becoming more and more recognized, and the recognition of gonadotropin receptor antagonists is also increasing, so that people who used to use oral contraceptives can now use these drugs more and more.

In that sense, the increase in the number of drugs with the same mechanism of action is a way to expand the market, and unless such a market expands first, there is little point in competing with each other. I think that's why Myovant made such a comment.

In its comment, it also said that the ACOG guidelines have been revised. So, in that sense, it is positive for us that treatment with drugs with this mechanism of action is becoming recognized and advanced in gynecology.

On the other hand, I think it is necessary for us to appeal for points of differentiation within the same mechanism of action.

Therefore, as was mentioned in the briefing session, I think the first step is to use the free program, or something like that, and let doctors and patients experience it, so that they can confirm the efficacy of the drug and move on to the next step.

I think that this way of entering the market will enhance the awareness of MYFEMBREE®.

As for what will happen in the future, Myovant is a publicly-listed company, so I would like to refrain from making any comments.

Questioner 2: I understand very well. Thank you very much. The third and final point is that Pfizer has decided not to exercise its option rights. I believe this was originally a one-time payment of USD50 million for exercising options, but was this USD50 million included in your company's guidance at the beginning of the fiscal year?

If you don't disclose this information, the upfront payment of JPY30 billion for ulotaront (SEP-363856) was probably included in the guidance at the beginning of the fiscal year because your company was negotiating quite a bit and had some control over it, and because there was a high possibility that it would be realized.

In terms of feasibility, I think it is a little difficult to see, because I think the exercise of these options is controlled by the other side rather than by your company.

In past cases, did your company incorporate these things into the guidance?

Nomura: Thank you very much. Pfizer's option rights of USD50 million are not included in our earnings forecast. This totally depends on Pfizer as to whether or not they are going to strategically invest in Europe and other regions as well. So, this is completely unpredictable. That's why we haven't factored it in.

However, for example, the lump-sum payment with Otsuka Pharmaceutical is a matter that we have been able to discuss directly with them. We thought we were able to include this in our forecast, so we did. Contractual options are at the discretion of the party, and we have no control over them, so we do not include them in our forecast.

We have been asked what we did with the USD50 million, but since the option rights with Pfizer still exist, we were not allowed to say anything about it. So, I said that I could not make any comments on that. It has become clear that the option with Pfizer is no longer available, so I think we are at the stage of disclosure.

Questioner 2: I understand very well. That is all from me. Thank you very much.

Questioner 3: I would like to begin by asking you to tell us about your partnership with Otsuka Pharmaceutical.

I believe that you are partnering with them because you can improve the total value of your products by doing so, and from what I have seen in the media, I understand that this partnership is positive for your company.

On the other hand, if I were to create a model based only on the information I have now, for example, for ulotaront (SEP-363856), based on your track record, I would have expected you to be able to launch it in the US and earn all the profits. But with this alliance, I think the profits will be split in half.

In that case, the value you contributed to your company will simply decrease even though I believe that the partnership was a positive thing for your company.

Therefore, I think that there are various factors that are important when looking at the value of this alliance, such as a decrease in short-term costs, a faster time frame, an increase in the number of indications compared to your company doing it alone, or an increase in the probability of success. Is it possible for you to tell us some additional information, other than simply halving your profits?

Nomura: Thank you very much. I think this is included in your question, but I can see it clearly when I look at the LATUDA® case. There were many twists and turns in the development of LATUDA® before we decided to develop it ourselves, and we were thinking about licensing it or not, and we decided to develop it ourselves by establishing a base in the US.

In the end, the LOE period is determined, so if a single company does it, for example, it can only be done sequentially. We worked on schizophrenia, and then on bipolar depression.

However, as you know, with schizophrenia alone, it has been approved as a drug and can help patients, but as a business, it is quite difficult. So, it's necessary to work on the second indication as soon as possible. However, if it is a single company, we can only do it in a sequential manner, which is difficult.

Therefore, if we did for bipolar depression earlier, we might have been able to raise the top line of JPY200 billion.

Therefore, if we were to work on ulotaront (SEP-363856) alone, we would have to work on schizophrenia in the same sequential manner, and then on indications, and in the meantime, even if expiration date of the substance patent came or was slightly extended, we would not have much time to spare.

However, if the two companies can work together and overlap the second and third indications to some extent, the potential of ulotaront (SEP-363856) will be even greater than it would be with a single company.

I think this is the mechanism.

Of course, since both companies will be working together, the cost of the project will be split in half, which decreases the cost compared to the case where each company were to work independently.

Therefore, in terms of time and cost, and the probability of success, we are struggling with the placebo effect in the neuropsychiatric area introduced earlier, but we have accumulated a lot of experience.

Otsuka Pharmaceutical also has a lot of experience in this area, having successfully developed Abilify.

Therefore, I think another advantage of this joint development is that the probability of success in clinical studies will be very high.

I believe that there will be synergies in sales activities by working together with Otsuka Pharmaceutical. This does not mean that Sumitomo Dainippon Pharma will suffer any disadvantages by splitting the profits and losses, but that there will be synergies by working together.

Therefore, Sumitomo Dainippon Pharma has decided to work together, even if two companies have to split the profits and losses, because Sumitomo Dainippon Pharma believes that two companies will be able to maximize the potential of ulotaront (SEP-363856) and other products in the pipeline.

Questioner 3: Thank you. I understand very well. Looking at the media, as for ulotaront (SEP-363856), the substance patent is for 2031, so the exclusivity period is not that long. From what you have just explained, I

understand that speed is important, so it is better to speed up the process and to be able to apply the technology in a variety of ways. So, you will increase the potential by expanding the indication.

Is it safe to assume that the area of profit gained will be larger than the case where you were to do it on your own?

Also, I got the impression from your explanation that SG&A and R&D expenses will not be reduced that much as a result of this alliance. I think this plan was included in the revised Mid-term Business Plan 2022 when it was explained to us.

At that time, we were told that R&D expenses would increase in the future, while SG&A expenses would be kept low. Is it correct to say that this partnership will not change your thinking much from what you told us in the explanation of the revised Mid-term Business Plan 2022?

Nomura: I think I said that expenses will remain the same until the end of the Mid-term Business Plan in 2022 but will be reduced after 2023. Therefore, the development cost will decrease after 2023.

SG&A expenses will remain unchanged, or rather, SG&A expenses will remain unchanged, and R&D expenses will be reduced from 2023 onward, as the three products of Myovant and Urovant will be taken off and will not require much additional cost.

Questioner 3: I understand very well. Thank you very much. Also, will the area of the profit gained by the partnership increase?

Nomura: As a matter of course, when we talk to the Board of Directors, we must ensure that the alliance is beneficial to us. As you mentioned, we simply cannot enter into an alliance that would be negative for us, and the Board of Directors would not approve it.

Therefore, as a result of various simulations and calculations, we decided that the alliance with Otsuka Pharmaceutical would be economically beneficial for us, and the Board of Directors has approved it.

Questioner 3: I understand. Thank you very much. Lastly, I believe that Gedeon Richter's royalties have been recorded by Myovant from this time, and it was mentioned in the explanation that the product has been launched in 7 countries in Europe.

Could you please comment on the situation in Europe, if possible?

That's all.

Nomura: I'm sorry. I do not have much knowledge about the markets covered by Gedeon Richter, so I am sorry that I cannot answer your current question.

Questioner 3: I understand. That's all. Thank you very much.

Questioner 4: You mentioned that coverage of GEMTESA® is low, but that Medicare coverage will increase from next January.

On the other hand, this is a benefit that is not anticholinergic, such as the absence of dry mouth or constipation. I thought that you had high expectations for this product. Is that correct? Is it reasonable to understand that information activities are a little stagnant in the midst of COVID-19?

Nomura: I think it was difficult to provide information in person in the COVID-19 situation. However, Urovant's sales reps are in charge of urology and long-term care facilities where there are elderly patients, while

Sunovion's sales reps, including about 90 people, cover primary care physicians. These sales reps will cover urology, long-term care, and primary care physicians.

As for the sales of GEMTESA®, we think there is no particular delay at this point. That's how I understand it, at least.

Questioner 4: I understand. Another product related to Myovant is ORGOVYX®. While Lupron is not supplied sufficiently, the benefits of switching to in-hospital prescriptions for oral drugs are not beneficial from the perspective of medical institutions or doctors.

I had heard that the bottleneck was how to attack that area. Could you tell us what you are doing about that, and how the situation is changing?

Nomura: Thank you very much. Leuprolide and injectable drugs can only be handled by medical institutions, so they will be dispensed by medical institutions. The economics of delivery price and insurance reimbursement price, or something like that, will be a very important point.

We understand this point very well. In the same way that Leuprolide is prescribed in the hospital, ORGOVYX® is basically prescribed in the hospital, and is delivered to medical institutions on an individual basis under a contract that is economically comparable. We are steadily working on such contracts.

Questioner 4: You mean in contracts with individual medical institutions?

Nomura: That is right.

Questioner 4: It's called a clinic. I understand. One more thing, in the President's earlier comment, it was said that the earnings forecast for this fiscal year has been left unchanged for the time being.

Nevertheless, even if we assume that the Mid-term Business Plan for FY2022 will remain unchanged, the environment will change considerably in the next 2 years, including the LATUDA® cliff and post-COVID-19.

In particular, there are new issues that need to be addressed, and if you say that these issues are incorporated in the Mid-term Business Plan 2022, that may be the end of it. But it is a review of the Mid-term Business Plan 2022.

If you have any thoughts on what the major management issues are, or if you have any ideas on what you are thinking about doing, I would love to hear them.

Thank you very much.

Nomura: In Japan, I think COVID-19 has improved a lot. But in the world, and in some other countries, it is still not so good. In addition, the business environment has changed before and after COVID-19. For example, even when it comes to visits to doctors, we don't expect the traditional way of doing things to return to normal.

So, as in Japan and the US, there will be a more hybrid approach, with in-person information delivery, online interviews, and online lectures.

In short, I think that we need to change the way we provide information to doctors and medical institutions in accordance with how they respond to COVID-19.

Therefore, we would like to proceed with the provision of such information after getting a good feel for the situation in the field. This is not a one-size-fits-all approach, and I think we have to think about what the best approach for each medical institution is individually.

Also, although it is not related to COVID-19, our major challenge in the future will be to further evolve the digital technology that we have acquired through alliance with Roivant, and to firmly incorporate new value creation processes that utilize data in our daily operations. That's what I'm aware of.

Questioner 4: I understand. Thank you very much.

Questioner 5: Thank you very much. I would like to ask you a few questions about your contract with Otsuka Pharmaceutical.

First of all, the development milestone is USD620 million. Of course, it is difficult for you to disclose the timing, but as you have been asked many times, I feel that they are very aware of the disadvantages of cutting your benefits in half. I would appreciate it if you could tell me how long you plan to keep the development milestone.

Nomura: We appreciate your question, but it is not possible for us to explain the details of each contract individually. There will probably be no such timing this year. Normally, in this kind of contract, milestones are received at the time of submission to the authorities or approval, so I think it would be better if you understand it that way.

Questioner 5: I see. Thank you very much. Another question. As you have introduced about synergies, and I am very sorry to put it this way, but Otsuka Pharmaceutical does not necessarily have the image of a global company that develops quickly, so there is a view that working with you may not necessarily speed up the process.

In order to eliminate this problem, I think it is necessary to accelerate the selection period for expanding the indication of development.

In this context, you have been looking at a relatively long time-frame for the launch of SEP-4199, but do you think there is a possibility that this alliance with Otsuka Pharmaceutical will accelerate that time frame?

Kimura: As for the future development plan of SEP-4199, we will be discussing it with Otsuka Pharmaceutical again in the future. The reason why the development of SEP-4199 seems to be taking a long time now is because of the previous phase, and also because we want to concentrate on ulotaront (SEP-363856).

So, we are now drawing a timeline with the plan to do Phase 3 one by one. The key point from now on will be how much risk we can take in that area and bring it forward in parallel or overlap it. So, if we do that, the approval period will be brought forward.

Questioner 5: Thank you. Another point, for the top line of the first Phase 3 of ulotaront (SEP-363856), it is still not clear when we should be looking at now. Should we assume it will be the period from January to March next year?

Kimura: The clinical study of ulotaront (SEP-363856) has been delayed slightly, but only by a few months, and we expect to see the results in the first half of the next fiscal year.

Questioner 5: I see. Thank you very much. That's all.

Questioner 6: Thank you very much.

On page 10, in your explanation of the contract with Otsuka Pharmaceutical, you mentioned that the implementation of clinical studies is divided by indication and that you are currently discussing how to divide the work. The cost is to be shared equally, so what we see and what comes out in the accounting is 50/50 for all the indications, but what is actually being worked on under the water is to be shared, is that correct?

Nomura: We are currently working on ulotaront (SEP-363856) for schizophrenia, so the second indication may be done by Otsuka Pharmaceutical, for example. However, the cost is half for schizophrenia and also half for the second indication. It is difficult for both companies to work together on the same second indication, so we divide the responsibility for each indication. The cost is to be split in half.

Questioner 6: Thank you very much. In the same idea, what do you think about the possibility of dividing the profits and expenses for activities and accounting purposes, and also for sales?

According to your previous explanation, there is a time lag between the expiration of the LATUDA® patent and the launch of ulotaront (SEP-363856). Normally, I think that the sales organization would shrink significantly when the LATUDA® patent expires. But since ulotaront (SEP-363856) is coming soon, it would be difficult to close the entire sales organization, even if it were to shrink.

This would inevitably cost your company a lot of money during that period. At this time, in the alliance with Otsuka Pharmaceutical, I think you can decide to have Otsuka Pharmaceutical do most of the sales activities at the launch stage of the ulotaront (SEP-363856) and share the costs for accounting purposes.

I thought that would make it possible for your company to greatly reduce costs during the intervening period, but what are you and Otsuka Pharmaceutical discussing now?

Nomura: Thank you very much. The connection between our LATUDA® sales reps and the ulotaront (SEP-363856) sales reps is a very important issue to be considered. I think there is a way of thinking, as you mentioned. As you mentioned, we would like to make the transition in a way that has as little impact on the bottom line as possible.

At this point, however, we do not have a concrete plan for how we will do this. It is still under consideration.

Questioner 6: I see. Thank you very much. That's all.

Harada: That concludes the question and answer session and today's meeting. Thank you very much.