Sumitomo Pharma

Sumitomo Pharma Co., Ltd.

Conference on Financial Forecasts Revision for FY2023 and Financial Forecasts for FY2024

May 1, 2024

Event Summary

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[Venue]	Webcast

[Number of Speakers]	3	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Senior Managing Executive Officer
	Naoki Noguchi	Executive Officer Corporate Governance; Corporate Communications Vice President, Head of Corporate Communications
[Analyst Names]*	Seiji Wakao	JPMorgan Securities Japan
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Fumiyoshi Sakai	UBS Securities Japan
	Hidemaru Yamaguchi	Citigroup Global Markets Japan
	Kazuaki Hashiguchi	Daiwa Securities
	Stephen Barker	Jefferies (Japan)
	Hiroshi Wada	SMBC Nikko Securities

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

Presentation

Noguchi: Now that it's time, we would like to start the briefing on Sumitomo Pharma Co. Ltd.'s financial forecasts revision for FY2023 and financial forecasts for FY2024.

Thank you very much for joining us today despite your busy schedules and the short notice. This presentation will be webcast live via Zoom webinar from our Tokyo Head Office.

After explaining all about the Company in accordance with the presentation materials posted on our website yesterday, there will be time for a Q&A. We look forward to your cooperation.

First of all, I would like to make an announcement and request to all of you. Please change the participant information displayed on your Zoom screen to your company name and your name.

I would like to introduce today's speakers from the Company. Mr. Nomura, Representative Director, President and CEO; Dr. Kimura, Representative Director, Senior Managing Executive Officer, and I'm Noguchi, Moderator.

Thank you.

Now, Nomura will explain the revision of the financial forecasts for FY2023 and the financial forecasts for FY2024.

Mr. Nomura, please go ahead.

Revisions to Forecasts of the Consolidated Financial Results for the Year ended March 31, 2024

(Millions of yen)

	Revenue	Core operating profit	Operating profit	Net profit attributable to owners of the parent	Basic earnings per share
Jan. 31, 2024 Forecasts (A)	317,000	(134,000)	(156,000)	(141,000)	¥ (354.90)
Revised Forecasts (B)	314,600	(133,000)	(354,900)	(315,000)	¥ (792.86)
Variance in amount (B－A)	(2,400)	1,000	(198,900)	(174,000)	–
Variance in percent (%)	(0.8)	–	–	–	–
[Reference] Previous year (Year ended March 31, 2023)	555,544	16,364	(76,979)	(74,512)	¥ (187.55)

Post the impairment loss totaling 180.9 billion yen in outside the core

- ✓ Patent rights impairment loss of MYFEMBREE®, amounting to $923M (133.5 billion yen, 93% decrease on a dollar basis)
- ✓ Good will impairment loss of North American business, amounting to $248M (35.9 billion yen, 10% decrease on a dollar basis)
- ✓ In-process research and development impairment loss of the discontinuation of development of compounds such as rodatristat ethyl and EPI-589, amounting to 10.6 billion yen

Post additional business structure improvement expenses of 8.7 billion yen in outside the core (totaling 30.1 billion yen)

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Nomura: Hello, my name is Nomura, and I am the president. Thank you very much for taking time out of your busy schedules today to attend our briefing.

Now that our time is limited, I will explain the situation based on the materials.

This has already been disclosed to you. In January, we announced our fiscal year 2023 forecasts in the Q3 financial results, and this time, compared to that, we are forecasting a decrease of JPY2.4 billion in revenue. The situation is that there has been a decrease in the North America and Japan segments.

On the other hand, the core operating profit will improve by JPY1 billion from the forecast. Although gross profit will decrease, the decrease in R&D expenses and SG&A expenses will be resulted in an increase of about JPY1 billion.

Then, at the operating profit level, we will post a significant loss of JPY354.9 billion, as this is written below here, which means that a total of JPY180.9 billion in impairment losses will be recorded.

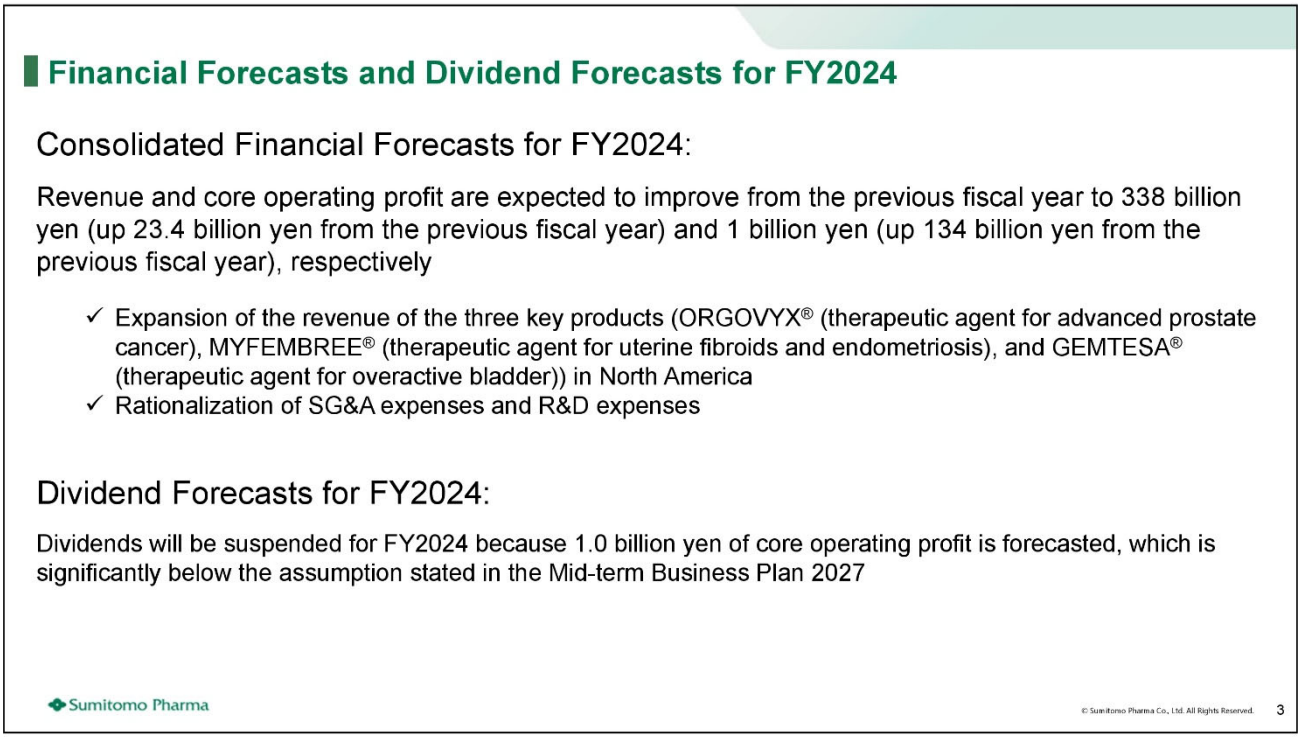
The breakdown of the impairment loss is, in addition to the estimated impairment loss, JPY10.6 billion for the discontinuation of development, including rodatristat ethyl and EPI-589, impairment loss for MYFEMBREE, and the impairment loss of goodwill of the business in North America due to reevaluation of the business in North America.

In particular, the performance of what we call the three key products, ORGOVYX, MYFEMBREE, and GEMTESA, continued to fall far short of our expectations.

Therefore, when we evaluated the North American business, we requested third parties to forecast our revenue in addition to our own revenue forecasts and various other assumptions. Based on this, we

reassessed the value of our North American business, and based on this, we wrote down the patent rights of MYFEMBREE and goodwill of North American business.

We are very sorry and take very seriously the fact that the loss attributable to owners of the parent for the current fiscal year increased significantly more than expected as a result of the large amount of impairment losses incurred.

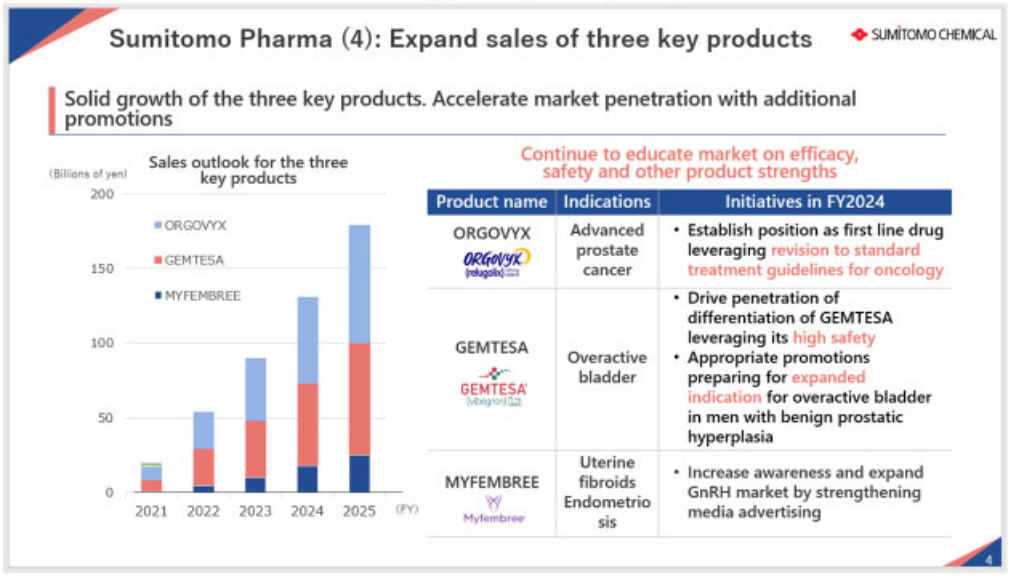


As you have probably already seen, for the fiscal year 2024, we are aiming for revenue of JPY338 billion and core operating profit of JPY1 billion. We know we are in a difficult situation, but we hope to somehow secure a profit of JPY1 billion.

This is predicated on expanding sales of our three key products in North America: ORGOVYX, MYFEMBREE, and GEMTESA.

Please refer to the slide on page nine to see a little more about this.

Appendix (Sumitomo Chemical: Investors' Meeting for the Current Priority Management Issues and Business Strategy on April 30, 2024)



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This is a time-series graph of these three products.

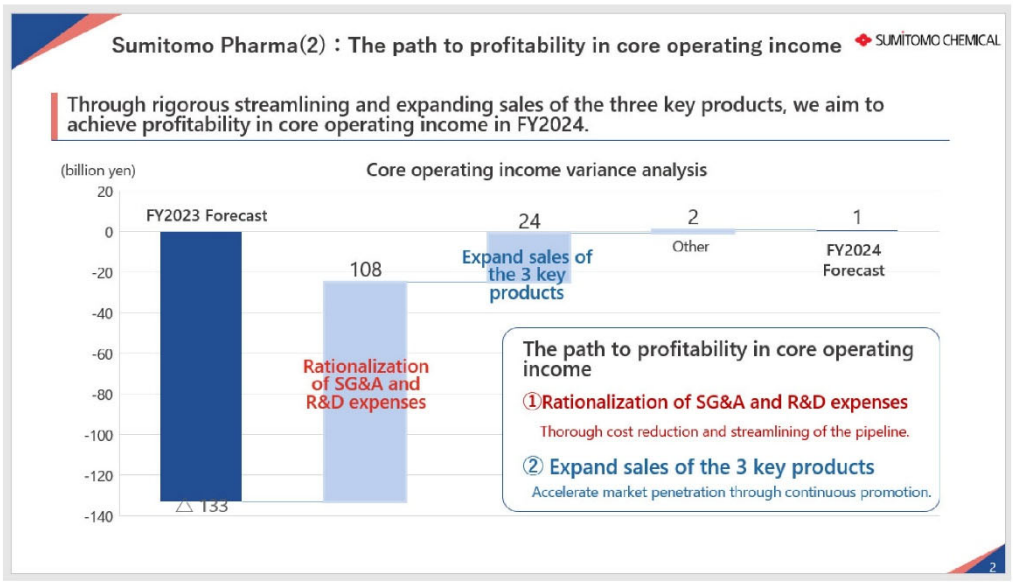
In 2023, the actual amount is estimated to be less than JPY90 billion, and we are planning to grow to JPY130 billion in FY2024 and JPY180 billion in FY2025. In 2024, as I mentioned, we are planning to secure profits based on revenue at the JPY130 billion level.

I would like to ask you to go back to where we were before.

I would like to explain later on the rationalization of SG&A expenses and R&D expenses.

Regarding the dividend for FY2024, our Mid-term Business Plan originally projected a core operating profit of about JPY40 billion. Under such circumstances, we have been talking about resuming dividends, but since the core operating profit is JPY1 billion, which is an extremely low level, we are now planning to defer a dividend payment.

Financial Forecasts for FY2024 (Core operating profit)



Source: Sumitomo Chemical Co., Ltd.
Investors' Meeting for the Current Priority Management Issues and Business Strategy on April 30, 2024

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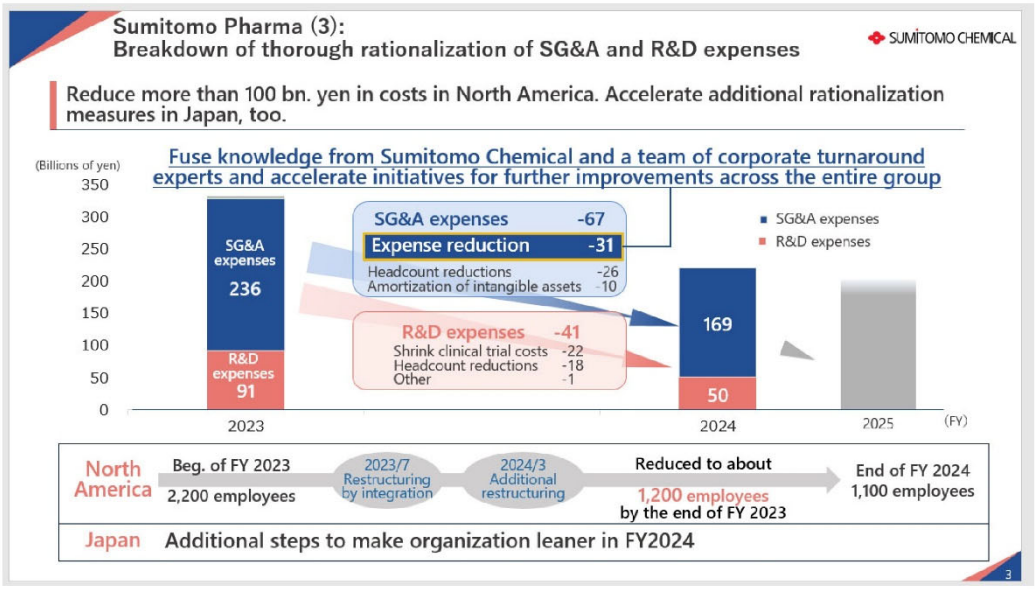
Now, I would like to talk a little bit about reducing SG&A and R&D expenses.

The core operating loss was JPYJ133 billion, which we will improve by JPY108 billion by improving SG&A expenses and R&D expenses.

Also, since the sales of the three key products I mentioned earlier are about JPY130 billion, this means that gross profit will increase.

We also have about JPY2 billion, and we are trying to achieve a core operating profit of JPY1 billion through a combination of these items. In particular, the rationalization of the JPY108 billion in SG&A and R&D expenses is a very serious matter, which I will explain on the next page.

Financial Forecasts for FY2024 (SG&A expenses and R&D expenses)



Source: Sumitomo Chemical Co., Ltd.
Investors' Meeting for the Current Priority Management Issues and Business Strategy on April 30, 2024

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In North America, the number of employees was originally 2,200 during FY2023 and was decreased to 1,200 at the end of FY2023, so it is assumed that the number of employees has already decreased by about 1,000. SG&A expenses decreased from JPY236 billion to JPY169 billion, a decrease of JPY67 billion.

There is a JPY26 billion reduction in personnel costs, and then for the amortization of intangibles, this is due to a decrease in amortization of intangibles as a result of the significant impairment of MYFEMBREE. Then, JPY31 billion in cost reductions will be implemented.

This is the material that Sumitomo Chemical used in its Investors' Meeting for the Current Priority Management Issues and Business Strategy yesterday, and we will continue to make further improvements to this JPY31 billion cost reduction and realize more reductions.

And also, R&D expenses are in the direction of a decrease of about JPY18 billion due to the fact that the number of personnel has already been reduced.

Then, we narrow down the cost of the clinical studies. The clinical study programs will be narrowed down to regenerative medicine/cell therapy and oncology in the late stage program, which will result in a significant decrease in R&D expenditures, with an overall decrease of JPY41 billion. This means a decrease of JPY108 billion in total.

In Japan, costs and budgets have been considerably reduced, aiming for slimmer costs and budgets. Furthermore, we are working to make more efficient use of the budget.

Through these efforts, we are trying to achieve a core operating profit of JPY1 billion by expanding revenue and reducing expenses.

The following pages and beyond are all for reference only, so that is all for my explanation.

Noguchi: Thank you very much, Mr. Nomura.

Question & Answer

Noguchi [M]: I would now like to move on to the question-and-answer session. The order in which we will take questions is by 1:50 PM, we will start with analysts and institutional investors, and then move on to questions from the Medicare.

If you have any questions, please let us know by pressing the raise-your-hand button on Zoom. Also, we would like to reiterate our request that you change the participant information displayed on your Zoom screen to your company name and your name.

The moderator will call out your name in turn and we will unmute the microphone, so please tell your name and affiliation, followed by your question.

Mr. Wakao from JPMorgan Securities Japan, please go ahead.

Wakao, JPMorgan Securities Japan [Q]: I'm Wakao from JPMorgan. Thank you.

The first question is that the forecasts for FY2024 was JPY1 billion for the core OP, I think. And then, what are your thoughts on whether you will be able to maintain this profit level or grow beyond the next FY2025?

Since you have made drastic cost reductions in your forecasts for FY2024, I think the key point will be whether you can achieve your forecast for the current fiscal year, but I also think the stock market is concerned about what will happen in the next fiscal year and beyond. Can you tell us what will happen in FY2025 and beyond, and whether this cost reduction will allow you to maintain a certain level of profit?

Nomura [A]: Thank you. Now, to answer your question first, we will continue to reduce costs under this system, so we will manage our business with very low costs.

On the other hand, revenue is a little lower than we had originally expected, but our three key products are growing. In FY2024, core operating profit will be slightly in the black, and will be even more profitable from FY2025 onward. That is what we are assuming.

Wakao [Q]: Thank you very much. I would like to know about the part on the ninth slide of the reference material, which is still important for growth in FY2025 and beyond. We have been given the prospect of ORGOVYX, GEMTESA, and MYFEMBREE, but I am not sure if this is feasible.

I understand that you are planning to do your best to achieve this goal, but I am still very concerned about whether or not this figure is achievable, given your past performance and the fact that your company's guidance has always been below the actual guidance.

In particular, the competitive environment for each drug and the circumstances in which they are placed are likely to change in the future, so I'm also interested in how you are taking these risks into consideration. So, I was wondering if you could tell me a little bit about the sales forecast for each of these drugs, including how you are taking the risks into account.

Sorry for this question being long, but as for ORGOVYX, I'm not sure if you anticipate the impact of the Medicare Part D reform. Also, please tell me if you are taking the generic impact of Astellas' Mirabegron into consideration for GEMTESA.

Nomura [A]: Thank you. First of all, though, let me first say whether it is taken into consideration or not. In the case of ORGOVYX, it is included, although the insurance reimbursement system has been changed since January. Then there is the inclusion in the NCCN guidelines that the status of the drug used to be that it was not recommended for ORGOVYX, but that is no longer the case, and the drug has been changed to one that is recommended for combination use.

As for the launching of the generic form of MYRBETRIQ, this is a very new story, and we are not yet sure what impact it will have on us. I suppose it is not included in this figure.

The revenue in 2024 and 2025 have already been released, and basically, as you pointed out earlier, there was a significant discrepancy between our initial forecast and actual results, and we took this very seriously and have been considering various ways of forecasting.

As for the revenue in 2024 and 2025, I guess you could call it a trend in revenue so far, but of course, a trend does not mean that sales are increasing without us doing anything. Naturally, the market has been growing to some extent as a result of various promotional activities, and we have added some of our own effort targets to this growth to make these figures.

When I mentioned earlier that we included third-party evaluations in the impairment assessment, it is true that there were significant differences between the third-party evaluations and ours for GEMTESA and MYFEMBREE, but for 2024 and 2025, there were not so many differences.

For our part, this figure itself is still at risk, although of course there is still the risk of the generic impact of MYRBETRIQ to GEMTESA. We recognize that this is a slightly different level of forecast than the guidance we have been producing.

Wakao [Q]: Thank you very much. Sorry, just for a follow-up. What I wanted to know a little bit about ORGOVYX was that the reform of that Medicare Part D will start next January, and I was wondering if the out-of-pocket fee of the patients will be affected or not, having been capped at $2,000. Is your commentary now about the impact of that?

Nomura [A]: For the time being, since January this year, the catastrophic coverage, the out-of-pocket fee of the patient on top no longer has to be paid by the patient, so in that sense, it is easier to use ORGOVYX.

Wakao [Q]: And as for the part about the $2,000 cap next January, I'm wondering if it will have that much of an impact because it's not as high as Astellas' XTANDI, for example. On the other hand, I'm still a little concerned about Medicare Part D because I think it is a big one. What do you think about that?

Nomura [A]: For our part, we don't think it will have that much of a negative impact. I think it will continue to depend on how, how shall I say it, or the patient, or the prescribing doctor, looks at it. We do not feel that it is that unfavorable in our view.

Wakao [Q]: Also, sorry, my question has been long. I think you picked up some more issues with this ORGOVYX and GEMTESA as of Q3, is it correct to understand that they are moving in the direction of improving?

You are assuming that the growth will be strong, but I cannot be reassured if the issues you mentioned in Q3 are not moving in the direction of improvement. So, would you tell me about it?

Nomura [A]: Yes, I think that ORGOVYX is working well within our assumptions at the moment, so I don't think there will be too many problems. GEMTESA's sales were slightly lower than we had expected, but we believe that this has already been factored into our revenue forecast for 2024 and beyond, so I do not think this will be a major problem.

Wakao [Q]: I understand. Sorry, let me ask a final question. On the eighth slide, you show us the drastic cost reductions that have been made this time. What does this figure of JPY169 billion for SG&A and JPY50 billion for R&D in 2024 look like? I would like to know a little more about it, if it can be qualitative.

Is this the minimum level of marketing for the three key products, and is it also the minimum level of Japan's current activities to a certain extent, although Japan could probably be slimmed down a bit more? Also, regarding R&D expenses, should we take it as a minimum figure to run the current pipeline? Please just tell me what this level is.

Nomura [A]: Thank you. Dr. Kimura will answer about R&D expenses. As for SG&A expenses, although we have drastically reduced the number of employees in North America, there is no way that we can reorganize our operations in such a way as to reduce sales of our three key products.

It is important for us not to lose sales of our three key products, and we are proceeding under the policy of further growth and expansion. We are also focusing on the divisions to be targeted for this reduction. We believe that the JPY169 billion in SG&A expenses will be sufficient to support sales.

Kimura [A]: I'm Kimura, and I would like to continue with the explanation on R&D expenses.

You may have had the impression that JPY50 billion is a large decrease from JPY91 billion. We are actually reducing it by that much, JPY41 billion, but in fact, we have changed the framework of our partnership with Otsuka, and we have stopped all development of ulotaront.

At the same time, the late-stage CNS-related development organization and its associated support organization in North America were streamlined in March of this year. This alone has led to a cost reduction of more than JPY20 billion.

Also, the backbone of this policy is to cut more than JPY10 billion from the current research themes. In this context, the budget for oncology and regenerative medicine/cell therapy has been allocated without reduction, as they are expected to be launched in the near future.

Some of the organizations were bloated when LATUDA was in place, so this year will be a bit difficult for these organizations, and we think it will be a year of streamlining, cutting waste, and allocating it on research and development.

In summary, we have allocated an adequate budget for what we are going to promote. As for the others, we are having a bit of a difficult time this year, but we have issued an order to eliminate waste, as this is a year of transition.

Wakao [Q]: I understand. Does that mean that R&D will increase a bit in the next fiscal year and beyond? According to what you are implying.

Kimura [A]: No, we are currently thinking about maintaining R&D expenses at this amount for the next fiscal year. However, we believe that by eliminating such waste, we will be able to make a little more space.

Wakao [M]: I understand very well. Thank you. That's all from me.

Noguchi [M]: Thank you very much. Next up will be Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka, Morgan Stanley MUFG Securities [Q]: Hello, this is Muraoka from Morgan Stanley. Thank you.

The first question is about the balance sheet. I understand that you have talked about the P/L for the next year or two, but I think that the capital has become much smaller due to the large impairment loss. How do you think you will deal with it?

Yesterday, Sumitomo Chemical mentioned that they would guarantee debts, etc., but do you envision that you will turn around your smaller capital through borrowing? Please let us know how you think about the balance sheet, including that point.

Nomura [A]: Thank you for your questions. As for the balance sheet, we have not yet finalized the figures, so we are not presenting them today. As you can imagine, this means that the Company has suffered a large amount of impairment, which means that there has been a significant damage to our net assets.

As Sumitomo Chemical explained yesterday, for the time being, we have cash on hand at the end of March and JPY98 billion from the sale of Roivant shares. And then there is the guarantee from Sumitomo Chemical, and then the support from banks. Our current thinking is that we will strive to recover our business performance as quickly as possible and restore our capital deficit by somehow turning around our capital needs through such efforts.

Muraoka [Q]: In other words, you don't envision a dilutive method at this time. Is my understanding correct?

Nomura [A]: At the moment, we are trying to recover our business performance with the support of Sumitomo Chemical, the banks, and our main bank.

Muraoka [Q]: I see. Thank you. This may be a bit of a flip side of this story, but in yesterday's talk by Sumitomo Chemical's President Iwata, he mentioned that there may be some discussion about partnering, etc., regarding the future of your company.

In other words, there was a nuance that he mentioned that Sumitomo Chemical's ownership ratio might change or decrease. You might tell me I should ask Sumitomo Chemical about that, but if there is anything your company can do, is thinking about, or would like to take in this or that direction, it would be very helpful to know.

Nomura [A]: I understand that in President Iwata's explanation yesterday, he said that he was not concerned about the investment ratio if Sumitomo Pharma had such a partner in the context of how to grow the Company in the future.

So, we would be very willing to consider such a proposal together very positively, if they have one. Of course, again, we are a publicly traded company, so I am sure we will participate in such discussions while also protecting the interests of minority shareholders.

Muraoka [Q]: Thank you. Does that mean, for example, that is not the story that they have been already approached with several attractive projects, instead of Sumitomo Pharma, and asked what they would like to do?

Nomura [A]: That is what President Iwata spoke about yesterday, I believe.

Muraoka [Q]: Are you saying that your company already has some sort of Plan A, B, and C?

Nomura [A]: No, no, no, President Iwata just said that such things could be considered if necessary for our growth, how I should put it. That is all I can say.

Muraoka [M]: I understand. Thank you. That's all from me.

Noguchi [M]: Thank you very much. Next, Mr. Sakai from UBS Securities Japan, please ask your question.

Sakai, UBS Securities Japan [Q]: This is Sakai from UBS. President Nomura, I'm sorry, this may not be even a question. My impression from Sumitomo Chemical's briefing yesterday was that they are also having a very hard time and that they do not have enough strength to support Sumitomo Pharma.

In the process, as you mentioned, there may be, for example, a reduction in equity as a result. And furthermore, there was mention of various things, such as considering partnering. I think this is a matter of course, but I would like to reiterate my understanding that President Iwata and President Nomura have already reached an agreement on this Plan A, which was announced this time, is that correct?

Also, with regard to cost reductions for the next fiscal year, since there will be personnel reductions, etc., am I correct in understanding that a significant portion of this has already been secured?

Excuse me, I'm going to ask all of these questions together. Dr. Kimura mentioned the reduction of R&D expenses, JPY50 billion, and I understand that you are planning to reduce this amount, but what will be left after the reduction? What kind of projects will you focus on?

You mentioned that oncology and regenerative medicine/cell therapy will remain, but I think it was also mentioned yesterday that regenerative medicine/cell therapy will be operated in the future through a joint venture with Sumitomo Chemical. Including that, I would like to ask if there is anything you can disclose now about your future R&D policy.

These are the three questions I would like to ask.

Nomura [M]: Thank you. Now, can you start with the last question for a moment, Dr. Kimura?

Kimura [A]: I'm Kimura. I would like to explain about R&D.

Regarding R&D expenses, we are considering JPY50 billion for the current and next fiscal years as a ceiling in the medium to long term, in FY2024 and FY2025. After that, we think we can increase it while monitoring the profit/loss situation.

Also, regarding the pipeline, we are focusing on allocating to oncology and regenerative medicine/cell therapy, but that is not the whole story. We are allocating budgets for early stage compounds of CNS or exploratory research, not JPY50 billion cuts, but JPY50 billion investment, and we are going to pay for research and development, but we are allocating budgets on the basis that we can bear the burden within the JPY50 billion.

On the one hand, this assumes that Sumitomo Pharma will conduct R&D in its current form, but on the other hand, Sumitomo Chemical has announced the externalization of regenerative medicine/cell therapy. We are beginning to discuss what form this should take.

When the new company becomes our minority-owned company, the cost of regenerative medicine/cell therapy will be removed from our R&D activities. It does not mean that regenerative medicine/cell therapy will completely disappear from Sumitomo Pharma's point of view; the new company will develop some of the products, while Sumitomo Pharma will be responsible for sales and other aspects of the business. We will work out the details of this.

We are also moving forward with this concept in the hope that the establishment of the new company will lighten the R&D burden, if only slightly.

Nomura [A]: And then, the cost reductions are based on a workforce reduction of about 1,000 people in North America. Then, based on the impairment of MYFEMBREE mentioned earlier, we are almost at the point where

we can see the realization of the project. There are some details that still need to be worked out, but we believe that most of them are feasible.

I am a little unclear as to which plan you were referring to in your first question.

Sakai [Q]: The plan that you announced this time, which includes this broad framework of cost reductions, this policy for FY2024, or should I say, the forecast of business performance.

I think that President Iwata's comments yesterday included the fact that he said that he would consider various things simultaneously in the process. Is it correct to say that you will be answering various questions during this term, including that at the same time?

When you mentioned about this as Plan A, I asked if there was a Plan B at the time of the Mid-term Business Plan, and you said there was no Plan B. I would like to know if my understanding is correct that the situation is the same this time, including that. Please tell me a little bit about the situation.

Nomura [A]: What Sumitomo Chemical explained at the Investors' Meeting for the Current Priority Management Issues and Business Strategy yesterday is, of course, what has been agreed upon with our company.

As for the partnering mentioned by President Iwata, this is something we will consider if we are asked; I think I cannot say specifically that there is such an agreement at this moment.

Sakai [Q]: I understand. So, you mean you are thinking about a lot of things that are currently in progress if you consider that during this FY2024.

Nomura [A]: If it is currently in progress, or, I mean we will consider and look into it if we are asked in the future.

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

Noguchi [M]: Thank you very much. Next, Mr. Yamaguchi from Citigroup Global Markets Japan.

Yamaguchi, Citigroup Global Markets Japan [Q]: Thank you very much. I'm Yamaguchi from Citigroup. I would like to ask you a few more questions on page eight, of the handout.

First of all, in the area of SG&A expenses, I believe that headcount reduction and amortization of intangible assets have already been done. Regarding this cost reduction, do you mean that this is a part that needs to be accumulated by doing various things during the term?

In that case, there is a lot going on, such as not decreasing as much as expected, there is inflation, there are a lot of U.S. costs, and so on. What would you say about this JPY31 billion, should we see that the risk of fluctuation is still there? First, please take a look at SG&A expenses.

Nomura [A]: Regarding SG&A expenses, there may be some concern about the exchange rate, but if the exchange rate does not change, we have already decided to reduce the amount by this amount in the budget. And how much more can we improve on that?

The impact of the exchange rate on this is something we really don't know, but barring that, we can achieve this. And we would like to try to reduce it a little more. This means something like that.

Yamaguchi [Q]: I see. I would also like to ask you about R&D expenses.

As you commented earlier, I heard that the budget is almost on track for JPY50 billion for the next fiscal year because of the reduction in clinical study costs and the minus JPY22 billion, which includes a number of changes in the framework with Otsuka. Is that correct?

Kimura [A]: As you understand, that is fine. We have already allocated the budget, so we believe we will be able to achieve this budget, although we have some activities in the U.S., which brings a little impact because of the exchange rate.

Yamaguchi [Q]: I see. And then as for Japan, you mentioned that the system will be further streamlined by the end of FY2024, is this included in this figure or not?

In particular, the number of MRs in Japan has been relatively large for some time, and in the case of your company, I think there was a part of it that you maintained, perhaps on purpose, in order to use them to sell your products in Japan or to introduce and sell your products.

Although this is happening in the U.S., the relative progress of cost reduction in Japan seems to be slower than in the U.S., considering the fact that considering the consolidation. Can you give us some specifics about the further streamlining in FY2024 related to MR, and how much of that is reflected in the figures for FY2024?

Nomura [A]: Yes, it says a further level of system streamlining. Basically, we are talking about a significant amount of cost savings being factored into FY2024, and that is still the level we are at here. However, we will be considering a variety of situations in the future, and I am sure that this further streamlining of the system will include a variety of things to be considered.

Yamaguchi [Q]: How about MR?

Nomura [A]: In short, I think there was an indication on, what do you call it, a suitable cost structure, or something like that, I think there is some part showing it on some pages.

If we, for example, introduce a variety of products or tie-ups, and we believe that there will come a time when we will have to review the scale of our business to a certain extent, given the timing of the introduction of various generic products.

In this context, from a comprehensive point of view, we will proceed with the further streamlining of the system, as it was written earlier, from a wide range of options.

Yamaguchi [Q]: I see. So, rather than FY2024, what will be done this fiscal year ending March 31, 2025, meaning FY2024, will have a reverse effect, or rather, a further effect, in FY2025 and onward.

Nomura [A]: I can't give you any specifics yet, but if we take various actions in FY2024, they will be reflected in FY2025, which will be the form we expect.

Yamaguchi [M]: I understand. That's all from me.

Noguchi [M]: Thank you very much. Next, Mr. Hashiguchi from Daiwa Securities. Please go ahead.

Hashiguchi, Daiwa Securities [Q]: I'm Hashiguchi. Thank you. I have several questions, but my first question is a continuation of what you just said, and I wonder if you could tell us again how you are thinking about your domestic business strategy.

In your previous explanation, you said that you would focus on in-licensing activities. From the point of view of the in-licensing source, the fact that the sales structure is well maintained would be a good reason to choose

this Sumitomo Pharma. I understand that you have been explaining to us for a long time that this personnel reduction was not expected.

In fact, I don't recall seeing many significant projects recently, and I have a feeling that even the companies that consider to create a marketing alliance of their products may be hesitant to offer them to you if their management seems to be in a state of flux.

I have the impression that the Company is changing course a bit, focusing on improving profit/loss, and taking streamlining into consideration. Is my understanding correct?

Nomura [A]: Thank you for your questions. I have already mentioned that our MRs are highly regarded by those outside the Company. In this context, we have been explaining that we will search for partnerships as much as possible, and will make the best use of our sales force.

However, if the products we are cooperating with, as I mentioned earlier, are to reach LOE or something like that, there is a possibility that the scale of our current products will change.

In the same way, as I answered your earlier question to Mr. Yamaguchi, we would like to consider various measures after taking a close look at the current domestic sales structure in a comprehensive manner, not only our sales system.

Hashiguchi [Q]: Thank you. Also, in your forecast of core operating profit for the period that began, do you anticipate any one-time gains, such as one-time gains from the sale of sold or matured products, or from the transfer of some rights to developing products?

Nomura [A]: Yes, as you mentioned, asset sales are factored into this to a certain extent.

Hashiguchi [Q]: Can you comment on the scale of the project, what you are thinking of doing, or how certain you are at this point?

Nomura [A]: Yes, we are going to sell the drugs which is in the time of LOE. We have been selling off items that have reached LOE, and we intend to do so in the same way.

In others, you know, there are 20 pluses, but there are some pluses and minuses there, so it doesn't mean that those 20 are in that area. I would like to explain a little more about the scale of the project in more detail in the earnings forecast on May 14.

Hashiguchi [Q]: Thank you. Finally, I'd like to ask about your company's commitment to the pipeline that you will be focusing on in the future. As for regenerative and cellular medicine, you mentioned earlier that the new company with Sumitomo Chemical will share the costs for some items. What are your thoughts on two items that are also on this slide in the back in the oncology area?

Will you be able to continue this on your own for the time being, or are you considering the possibility of bringing in outside funding?

Kimura [A]: Thank you very much for your question. Your understanding of regenerative medicine is as you said, and we believe that we can proceed with the oncology area as well, first of all with our R&D funds for the time being.

However, as you know, in the case of oncology, we will be running a number of clinical studies for combination therapies, and in such cases, we are considering talking together with the company that owns the combination drug.

At present, we are not focusing on out-licensing DSP-5336 or TP-3654 itself.

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

Noguchi [M]: Thank you very much. The next question is from Mr. Barker from Jefferies.

Barker, Jefferies (Japan) [Q]: Stephen Barker, Jefferies. Thank you.

I would like to ask you about your partnership with Pfizer. I believe one of the assumptions of the original Mid-term Business Plan was that you expected to record sales milestones related to ORGOVYX and MYFEMBREE this fiscal year. I would first like to ask if the new forecast for this fiscal year, which you are presenting here, includes such milestones.

Please let me know if you are expecting such milestones, if not this year, then next year or the year after that.

Nomura [A]: Regarding milestones, our assumption is that there are no milestones from Pfizer in FY2024 and that they will come in in FY2025.

Barker [Q]: How much are you anticipating in terms of money?

Nomura [A]: I'm sorry, I can't disclose the amount because of the agreement with Pfizer.

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

Noguchi [M]: Thank you very much. Now, Mr. Wada of SMBC Nikko Securities, please ask your questions.

Wada, SMBC Nikko Securities [Q]: I am Wada from SMBC Nikko Securities. Thank you. I would like to ask you about the sales of these three key products, and about sales further down the road.

When you originally revised the Mid-term Business Plan a year ago, I think you were looking at about JPY500 billion for FY2027. I would like to ask how much you are currently looking at with these three key products.

As for MYFEMBREE, I'm pretty sure it's 90% impaired, so I'm wondering if you've lowered their peak sales or not. Can you please tell us forecast for ORGOVYX and GEMTESA, including how you see they are changing?

Nomura [A]: Thank you for your question. As I mentioned earlier, we used a third-party evaluation to calculate the impairment, so in that sense, we do have the figures.

However, that means that we used a third-party neutral evaluation in assessing impairment, so we, as us, will have to consider this separately as to what goals we should achieve.

Although we have not yet announced it to the public, we are thinking that we need to review the contents of the Mid-term Business Plan announced in April of last year.

In this context, we would like to reconstruct our sales target, so I would like to refrain from saying what the figure would be at this stage, because it would be too easy for the figure to become an arbitrary figure.

We would like to review the Mid-term Business Plan as soon as possible.

Wada [Q]: Thank you very much. Also, I would like to ask you one more point. I think you mentioned that the sales structure, the sales structure in the U.S., has been revised considerably, and that sales of these three key products will grow. You have reduced your workforce by about half, but even so, I am sorry to repeat this question, but is it still possible to achieve this increase in sales?

Nomura [A]: Thank you for your question. The reduction in personnel is focused on the late-stage development of CNS in North America, general administrative personnel, and sales back-office personnel.

As for the sales people, the back office is originally organized like a collection of various companies. We have reduced the number of employees from the viewpoint that some of them were originally overstaffed. However, we are not reducing the actual marketing or sales personnel, so I think we can achieve these sales.

In the U.S., there are various TV commercials and such, and it is said that such things cost a lot of money. Rather than TV commercials, it would be more effective to create touchpoints through social networking sites or YouTube, which would not cost as much money. This is what we are thinking about.

So, in conclusion, we do not believe that there will be any significant downside impact on the sales structure at all as a result of this drastic reduction in personnel. This reorganization was originally conceived with this in mind.

Wada [M]: Okay. Thank you.

Noguchi [M]: Thank you very much. As your time has come, this concludes the Q&A session for analysts and institutional investors. Analysts and institutional investors are welcome to leave Zoom at their convenience.

From here, we would like to take questions from the media. For those on Zoom who have any questions, please click the raise-hand button. We will call your name and unmute the microphone. We would appreciate your affiliation and name followed by your question.

The first question is from Ms. Hyodo of Toyo Keizai. Please.

Hyodo, Toyo Keizai [Q]: I am Hyodo from Toyo Keizai. Thank you. It sounded to me earlier that you reviewed the way you forecast sales of the three key products, and I would like to know if that is correct and how you reviewed it.

Nomura [A]: Thank you. I don't know how to put it, but in the past, we have always valued highly the differentiating factors between ORGOVYX, MYFEMBREE, and GEMTESA from other products.

For example, in the case of hormone-sensitive prostate cancer, most of the drugs are injection, but ORGOVYX was the only oral drug available. Since more than 60% of the patients want to treat with an oral drug, we thought it would be better for the patients to receive it.

As for MYFEMBREE, there are concerns about the effects on bone density of this type of drug. However, with our MYFEMBREE, there is such a differentiating factor that bone density is hardly affected.

GEMTESA has various differentiating factors, such as no QTc prolongation, can be prescribed for hypertensive patients, and has a very good drug-drug interaction profile compared to competing drugs. We had assumed that we recognized that the drug had a very high potential.

If we talk about the sales forecast for 2024, this is basically based on the trend in 2023. As I mentioned earlier, the trend does not mean that sales will increase even if the Company leaves it alone; of course, it is assumed that sales will increase through promotion. We are also putting some of our own targets of effort on top of that. The forecast was made in such a way that it is closer to the actual situation, I guess.

As a corollary, we have just had a third party evaluate the impairment, and the figures for 2024 do not differ that much from the previous year. We assume that the probability of achieving these sales will be higher than previously expected.

Hyodo [Q]: Thank you very much. Sorry, one more point. I am talking about the domestic workforce reductions mentioned earlier. According to Sumitomo Chemical's explanation yesterday, the figures for this fiscal year include the personnel reduction at Sumitomo Pharma, which will probably performed in H2 of the fiscal year. I was wondering if my understanding was correct.

Is it that what is factored in this plan is mainly MRs, as you explained earlier, and other departments and such have not yet been considered?

Nomura [A]: I'm sorry, but I'm not aware of any mention in Sumitomo Chemical's explanation that Sumitomo Pharma will be reducing its workforce in Japan, so I'm afraid I can't give you an answer to that question.

Hyogo [Q]: I understand. I understand. Talking about the possibility of MRs.

Nomura [A]: MR, or as I mentioned earlier, the scale of the business, the Japanese business, it's not that the Japanese business is run solely by MRs. In short, we need to look at the things in relation to the scale of the Japanese business, and we have been asked this question several times so far, and I have said that we will consider various best measures in this context.

Hyodo [Q]: At this point, are you saying that the effect of the domestic workforce reduction has not been factored into the reduction of SG&A and R&D expenses?

Nomura [A]: There is nothing like that in this earlier, in these figures. This means that the domestic cost reduction efforts to date have been incorporated into the figures.

Hyodo [Q]: This will already be in effect from the beginning of the term.

Nomura [A]: These figures incorporate the reduction efforts that have been made since the beginning of the fiscal year. This is the background of it.

Hyodo [M]: Yes, sure. Thank you.

Noguchi [M]: Thank you very much. Please continue, Mr. Ishii of Kyodo News.

Ishii, Kyodo News [Q]: My name is Ishii from Kyodo News. I would like to confirm some figures again regarding the scale of the personnel reduction.

You mentioned that the total number was about 4,000 at Sumitomo Chemical, but can you give us an idea of the scale of your company's workforce in total in the U.S. and Japan?

Nomura [A]: I believe that the 4,000 people explained by Sumitomo Chemical include from 2,200 to 1,100 people, as you can see in this table, so I believe that 1,100 people have been factored in, and that is the understanding.

Ishii [Q]: You have mentioned this many times before, but is my understanding correct that you are not thinking of reducing the workforce in Japan yet?

Nomura [A]: As I mentioned in my earlier question, the expenses here do not include such personnel reductions in Japan.

Ishii [Q]: I see. So basically, you will reduce the workforce mainly in the U.S.

Nomura [A]: No, it's not that we are reducing the number of people, but we have already done most of the work, although there is a little more this fiscal year.

Ishii [Q]: It has already been done.

Nomura [A]: Yes.

Ishii [Q]: I understand. So, there will be no change in employment at the Suzuka Plant and other domestic departments for the time being, is that correct?

Nomura [A]: No, I think that here, what do you call it, I think I answered this question before.

As I mentioned earlier, there is a possibility that some of the products that we have partnered with in various sales will be reaching LOE in the near future. I think it is necessary to look at the Japanese business as a whole, and to make the structure appropriate to the scale of the business. I said that we think we have to take various steps to achieve this.

Ishii [M]: I understand. Thank you.

Noguchi [M]: Thank you very much. Please continue, Mr. Suwa of the Asahi Shimbun.

Suwa, the Asahi Shimbun [Q]: This is Suwa from the Asahi Shimbun. I have two questions: the first question is whether or not you are thinking of reducing the interest-bearing debt, which I think is around JPY400 billion, and how to reduce it.

Another question is that Sumitomo Chemical has a 51.6% stake in the Company, but if there is any discussion with Sumitomo Chemical about, for example, lowering their stake, I would like to ask you these two questions.

Nomura [M]: What is your intention in reducing borrowings?

Suwa [Q]: For example, how could JPY400 billion be reduced by, say, JPY30 or JPY50 billion.

Nomura [M]: By compressing, do you mean, in essence, repaying the loan?

Suwa [Q]: Yes.

Nomura [A]: Of course, we will continue to make steady repayments, as I mentioned earlier, as I mentioned earlier in the session. For our part, as we recover our business performance, we will also be able to turn around our cash. We also sold our shares in Roivant and have about JPY98 billion on hand, so we will use this to reduce our borrowings. This is what we are thinking.

Suwa [Q]: And isn't there some kind of asset sale?

Nomura [A]: In terms of asset sales, we have already sold our shares of Roivant in the current fiscal year, so that is an asset sale.

Suwa [Q]: And also real estate.

Nomura [A]: No, I was referring to it, as I was asked earlier about the drug reaching LOE, and I mentioned the sale of pharmaceuticals.

Suwa [M]: I understand.

Nomura [A]: From the perspective of improving cash flow, if there is a possibility that we could sell something, we would like to consider that again.

Suwa [M]: I understand.

Nomura [A]: As for Sumitomo Chemical's shareholding ratio and so on, it was asked at yesterday's briefing. I believe that it was only from Sumitomo Chemical's point of view, and it was a way of saying that they are not particularly concerned about the investment ratio, as long as it contributes to Sumitomo Pharma's growth in the future.

However, we do not know at this time when such a thing will happen, so there is no way of saying. However, if we receive such an offer, we will positively consider it. That is our thought.

Suwa [M]: I understand. Thank you.

Noguchi [M]: Thank you very much. Please continue, Mr. Kume of the Yomiuri Shimbun.

Kume, the Yomiuri Shimbun [Q]: My name is Kume from the Yomiuri Shimbun. I would like to ask you about overall situation. Frankly speaking, I would like to know how you, the president, perceive the current situation, in which the final deficit has spread to JPY315 billion, and what are your thoughts and feelings about the current situation?

Nomura [A]: I mentioned the current situation when I explained the forecast figures at the beginning of this presentation. We have done everything we can to grow the Company using shareholders' funds. Unfortunately, we have incurred a major impairment, for which we are truly sorry, and we take this matter very seriously.

Kume [Q]: Also, may I ask you to go back to the slide on page eight?

This is it. If you are going to reduce personnel to 1,100 in North America, does that mean that over the course of a year, another 100 employees will be reduced in North America, is this correct?

Nomura [A]: Yes, that is correct.

Kume [Q]: Regarding the expression "streamlining" in Japan, I think it has been mentioned many times before, or you referred to the expression of “compressing the cost.” How should I recognize this streamlining of the system more specifically; what will you reduce?

How much of this reduction, for example, is incorporated in SG&A and R&D expenses? Please tell us about the effects in Japan, if any, in the hundreds of millions of yen specifically.

Nomura [A]: Well, you are asking about the effect in Japan, and I'm not sure how much of that is in Japan; it's already included in the JPY31 billion in SG&A expenses.

I understand that a considerable cost reduction is incorporated in the slimming down process. That is all I can say at this stage. For our part, we have factored in very large reductions in North America, so I hope you understand that we are working on that in the domestic budget as well.

Kume [Q]: Also, regarding the future of the three key products, I think there was a slide that showed those three key products. You are talking about expanding sales by doing promotions in the future. You mentioned the use of SNS, but what kind of promotion will you use in the back office, and with the overall personnel shrinking?

I know that you have been doing promotions in the past, but if there is anything that you would like to change in order to continue to grow steadily in the future, please tell us again.

Nomura [A]: OK. How can I put it? Promotion naturally means providing information about the potential of the drug based on the results of clinical studies. Unlike Japan, it's not universal health insurance, so, for example, there is a certain amount of burden of expense on patients in the case of ORGOVYX.

However, as the insurance and reimbursement systems are changing, the size of individual payments for cancer patients is also decreasing.

As I also mentioned, there is also a preference for tablets rather than injections to a certain degree. However, this information is not always well communicated to the patients.

For our part, we need to communicate the benefits of ORGOVYX, or should I say, awareness of the benefits to the patients. Of course, we need to promote our products to the doctors, but we recognize that we first need to increase awareness of our products to patients.

That is, whether it is MYFEMBREE or GEMTESA, it is still not necessarily well recognized as an available treatment option, for example, with MYFEMBREE.

It is also written here that improvement of awareness, this is for a patient, right? Female patients suffering from uterine fibroids and endometriosis are not yet fully aware of the options available to them. We will try to provide such patients with as much information as we can.

As for GEMTESA, there is a high level of differentiation, but we also need to promote it to patients and provide them with information about the options available to them.

While it is important to provide information to doctors, we would like to create a situation in which patients can tell their doctors that they have such prescription options and would like to try them. I think this is the direction we should take.

Kume [Q]: I think this might be a little difficult to answer, but I was wondering if you are talking about the partnering or affiliation from earlier. You also mentioned that if there is an offer, you would consider it positively, but what is the time frame for this? And if there is already an offer, will you accept it during this term? Is there any time frame already in your mind?

Or it's competition, or maybe a pharmaceutical manufacturer, or maybe a fund of some sort. Please let me know if there is any image that you seem to hold.

Nomura [A]: Thank you for your question. Perhaps that partnering that Sumitomo Chemical mentioned at yesterday's briefing is not just a matter of money, but also of the various, for example, shortage of pipeline that will allow us to grow in the future.

So, I am not sure of the details of the explanation discussed yesterday, but I think that the candidate partner would be someone who has a pipeline that we can use effectively.

Kume [Q]: Is there anything about the timing?

Nomura [A]: As for the timing, this is just a matter of when such an opportunity arises, so we are not going to say at what timing.

Kume [M]: Okay. Thank you.

Noguchi [M]: Thank you very much. Since we have five minutes remaining, I would like to ask one question from each of you from this point on.

Next, Mr. Ishii of the Iyaku Tsushinsha, please continue.

Ishii, the Iyaku Tsushinsha [Q]: I am Ishii from the Iyaku Tsushinsha. I have one question. In FY2024, you will turn a profit of JPY1 billion, and I would like to ask President Nomura again how he feels about that. Then I'd like to ask you to tell us about your future prospects, if you can talk about it.

Nomura [A]: We will have a surplus of JPY1 billion for the current fiscal year and that we have a rough idea of what the cost reductions we talked earlier will be, so we have a certain degree of confidence in our cost estimates.

But, of course, that earlier point about sales not being that different from the third party's view, we will manage to achieve that as well. Then, based on the sale of the drugs that reached LOE and other such things, we hope to somehow achieve the JPY1 billion mark.

However, as there was a question earlier, in terms of GEMTESA, given the fact that the generic MYRBETRIQ is coming out and so on, and that it is not yet necessarily on board with respect to sales and earnings. Since the profit is within a very narrow range of JPY1 billion, we would like to make efforts to reduce costs in various areas so that we can absorb such risk factors. With this in mind, I would like to work hard over this year.

Ishii [M]: Thank you very much.

Noguchi [M]: Thank you. Next, Mr. Misumi from Nihon Keizai Shimbun.

Misumi, Nihon Keizai Shimbun [Q]: Misumi. I will ask just one question. At the Sumitomo Chemical briefing yesterday, there was talk about sending in directors, but this is a bit of a tough question, how do you hold the management team accountable? Please let us know what you think at this point.

Nomura [A]: As you pointed out, I take recent performance very seriously. However, what can I say, I would like to refrain from discussing anything further at this time.

Misumi [Q]: For example, I know that you have announced before that you were reducing your own compensation. What sort of responsibility do you think about like this?

Nomura [A]: I believe there will be another time when we will disclose the reduction in compensation, and we will let you know at that time.

Misumi [Q]: So you are saying that reductions will be made?

Nomura [A]: It will be reduced, or rather, it has been reduced for a long time, and I think it will be a question of how much more will be added to that.

Misumi [Q]: Okay. Thank you. I understand that you will explain the amount again.

Nomura [A]: I believe there is a separate timing to disclose the amount, or rather the percentage.

Misumi [M]: I see. Thank you.

Noguchi [M]: Since our time is up, I would like to call the last one, Mr. Matsuda from Yomiuri Shimbun, please.

Matsuda, Yomiuri Shimbun [Q]: I am Matsuda of the Yomiuri Shimbun. Excuse me, I would like to ask you about the 11th slide, the part about regenerative and cellular medicine. Sumitomo Pharma, you mentioned that the new company will be established by the end of FY2024, but I would like to know around when you are planning to establish the new company in FY2024, and if you have a business target.

Also, with regard to Parkinson's disease and retinal pigment epithelium tear, some clinical studies have already been completed and some company clinical studies have started under the leadership of Sumitomo Pharma, but am I correct in understanding that the new company will take the lead in future clinical studies and applications for approval of the authorities? Thank you.

Kimura [A]: This is Kimura. First of all, we are working on clinical studies, and in particular, this year, we are moving forward with the major goal of obtaining approval for the world's first iPS cell-derived product for Parkinson's disease, and if we proceed with the establishment of a new company for this purpose, we will not be able to meet the time frame at all.

As the Company, we will proceed according to the existing schedule. Clinical studies will soon begin in earnest in Japan and the U.S., and we are considering moving forward with these studies as well.

The establishment of the new company is intended to accelerate regenerative medicine, so we will consult with Sumitomo Chemical on the specific timing of when the new company can be established.

Matsuda [Q]: Okay. I would like to confirm that Sumitomo Pharma will continue to take the lead in the application for approval and clinical studies for Parkinson's disease, as it has in the past.

Kimura [A]: Yes, Sumitomo Pharma is currently playing a central role in the program, and it would be very difficult in practice to move the new company in the middle of the program, even if it is established. We will often make adjustments so that there are no discrepancies in our plans.

Matsuda [Q]: Okay. Also, just to confirm, am I correct in understanding that there is no change in the R&D expenses and pipeline for regenerative medicine and cell therapy?

Kimura [M]: Do you mean for this fiscal year?

Matsuda [M]: This fiscal year, yes.

Kimura [A]: Yes, no change. Sumitomo Chemical has commented that R&D expenses will increase as this area is enhanced in the future. We have been discussing this with Sumitomo Chemical in the light of our current situation, and we have decided that our financial situation must not become a limitation.

This year, the budget allowance has already been completed and things will proceed as planned. However, it is our intention to establish a new company and make the transition by the end of the fiscal year.

Matsuda [M]: I understand. Thank you.

Noguchi [M]: Thank you very much. Since the time is up, this concludes the presentation on Sumitomo Pharma's financial forecasts revision for FY2023 and financial forecasts for FY2024.

Thank you very much for joining us today.

[END]