Mitsubishi Tanabe Pharma Corporation

FY2018 Business Results

May 13, 2019

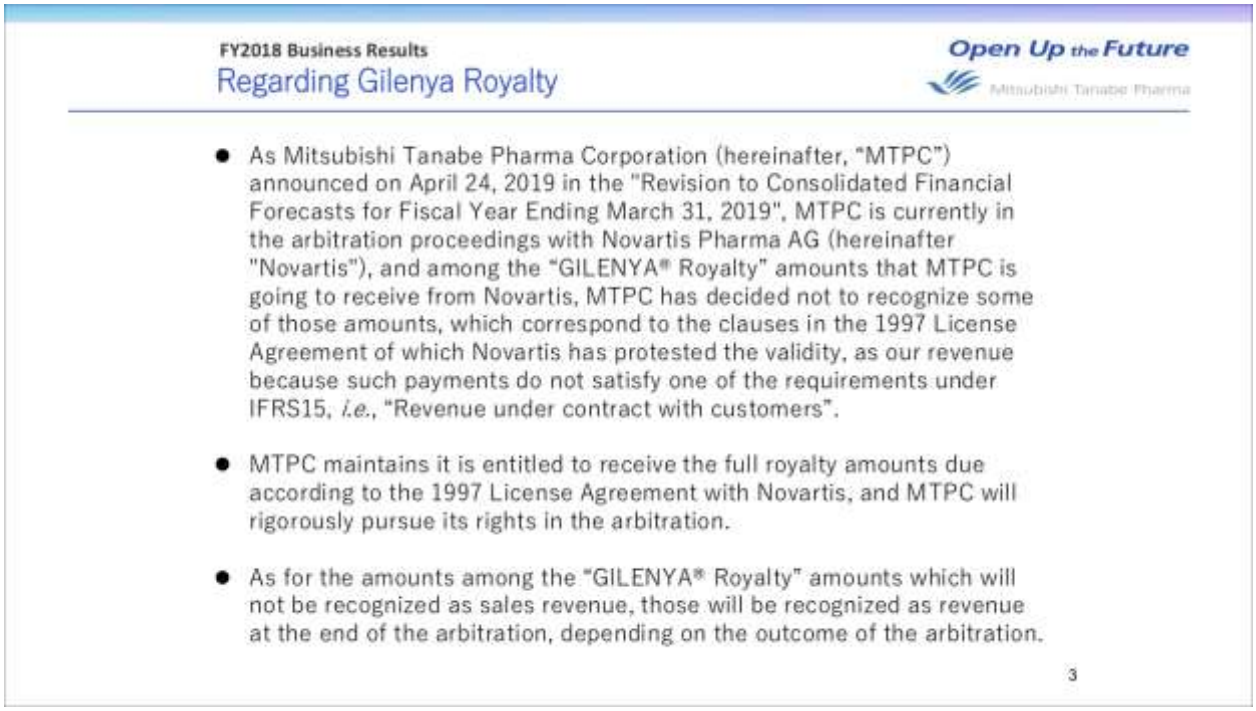
Event Summary

[Company Name]	Mitsubishi Tanabe Pharma Corporation
[Event Type]	Earnings Announcement
[Event Name]	FY2018 Business Results
[Fiscal Period]	FY2018 Annual
[Date]	May 13, 2019
[Number of Pages]	28
[Time]	13:00 – 13:55 (Total: 55 minutes, Presentation: 24 minutes, Q&A: 31 minutes)
[Venue]	17-10 Koamicho, Nihonbashi, Chuo-ku, Tokyo, 103-8405
[Venue Size]	250 m^2
[Participants]	approximately 60
[Number of Speakers]	4

Masayuki Mitsuka	President & Representative Director, CEO
Eizo Tabaru	Member of the Board, Managing Executive Officer, CFO
Yoshihiro Kobayashi	Managing Executive Officer, Head of Ikuyaku, Integrated Value Development Division
Yasutoshi Kawakami	Executive Officer, Head of Sales & Marketing Division

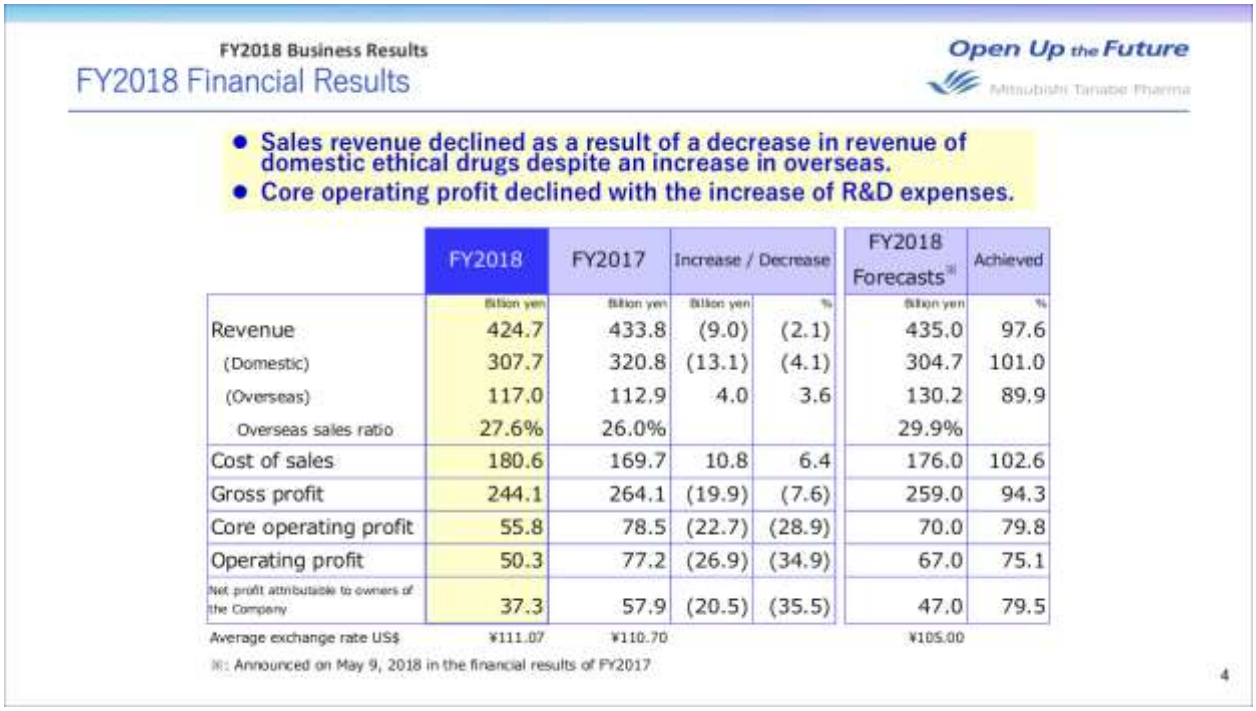
Presentation

Mitsuka: Ladies and gentlemen, I am Masayuki Mitsuka, the president and representative director of Mitsubishi Tanabe Pharma Corporation. Thank you very much for joining us for the briefing of the business results of fiscal 2018 of our company. I will explain about fiscal 2018 business results, the forecast for fiscal 2019, and the strategy to restore business growth, as well as returns to shareholders.



First on the fiscal 2018 business results, let me first discuss Gilenya royalty before I move into the presentation. As some of you may already know, as was announced on April 24, 2019, in the revision to consolidated financial forecasts for fiscal year ending March 31, 2019, we are currently in the arbitration proceedings with Novartis Pharma. And among the Gilenya royalty amounts that we are going to receive from Novartis, we have decided not to recognize some of those amounts as our revenue, in accordance with IFRS 15.

We maintain that we are entitled to receive the full royalty amounts due according to the license agreement. And we will rigorously pursue our rights in the arbitration. The Gilenya royalty amounts which will not be recognized as sales revenue, will be recognized as revenue at the end of the arbitration, depending on the outcome in that particular fiscal year. I would like to ask for your kind understanding on this matter.



FY2018 Business Results

FY2018 Financial Results

Open Up the Future

Mitsubishi Tanabe Pharma

- **Sales revenue declined as a result of a decrease in revenue of domestic ethical drugs despite an increase in overseas.**
- **Core operating profit declined with the increase of R&D expenses.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	424.7	433.8	(9.0)	(2.1)	435.0	97.6
(Domestic)	307.7	320.8	(13.1)	(4.1)	304.7	101.0
(Overseas)	117.0	112.9	4.0	3.6	130.2	89.9
Overseas sales ratio	27.6%	26.0%			29.9%	
Cost of sales	180.6	169.7	10.8	6.4	176.0	102.6
Gross profit	244.1	264.1	(19.9)	(7.6)	259.0	94.3
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8
Operating profit	50.3	77.2	(26.9)	(34.9)	67.0	75.1
Net profit attributable to owners of the Company	37.3	57.9	(20.5)	(35.5)	47.0	79.5
Average exchange rate US$	¥111.07	¥110.70			¥105.00	

※: Announced on May 9, 2018 in the financial results of FY2017

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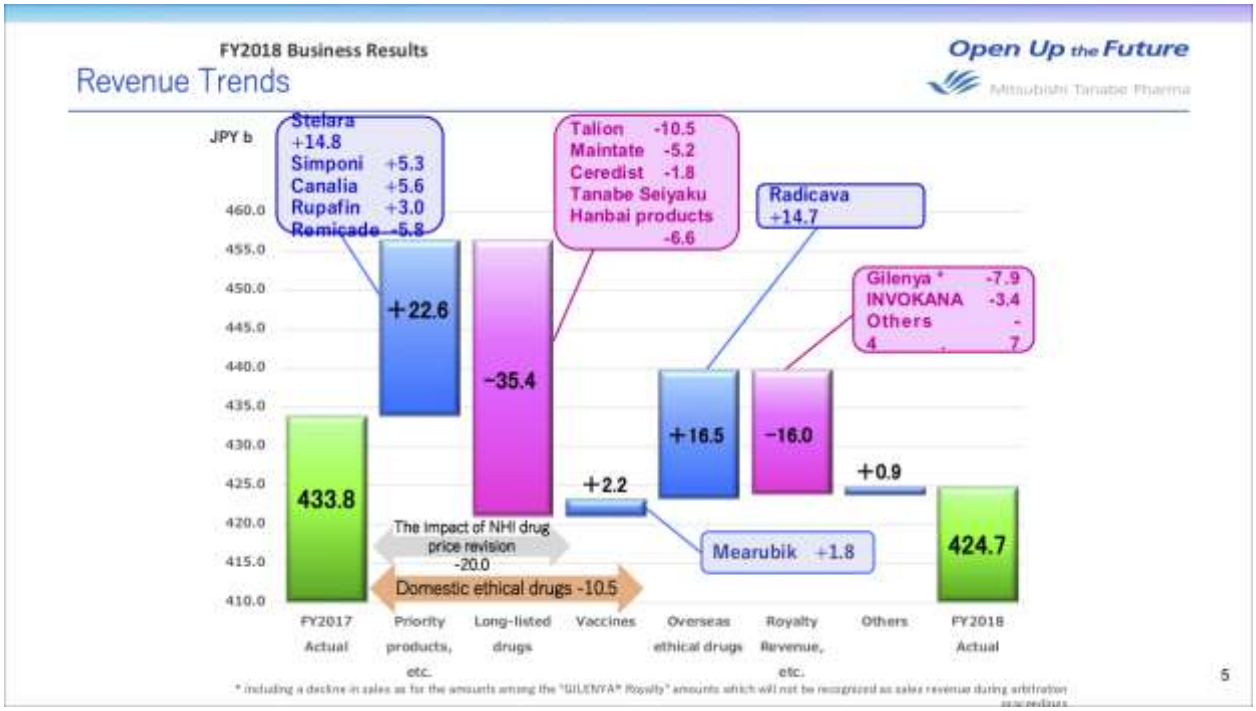
The sales revenue declined by 9 billion yen, or 2.1%, to 424.7 billion yen, as a result of a decrease of 13.1 billion, or 4.1%, in revenue of domestic ethical drugs, despite an increase of 4 billion, or 3.6%, in overseas. The core operating profit declined by 22.7 billion yen, or 28.9%, to 55.8 billion yen because R&D expenses increased as we accelerated investments for early recovery in profitability and future growth. As a result, the net profit attributable to owners of the company came to 37.3 billion yen, down 20.5 billion yen, or 35.5% year-on-year.



Next, on the revenue trends, among the priority domestic products, in the immunoinflammatory area, we have seen contribution from Stelara as we changed the sales framework with Janssen Pharma since July 2018, as well as from the growth in Simponi.

In diabetes area, Canalia fixed-dose combination, among others, grew. And this resulted in a positive impact of 22.6 billion yen. On the other hand, the sale of domestic ethical drugs declined by 10.5 billion yen year-on-year, due to NHI drug price revisions, decreased revenue in long-term listed products, and impact from transferring the generic businesses, as the business still contributed for half of the year in the previous fiscal year. But that was gone in fiscal 2018.

In overseas ethical drugs, Radicava went into the second year since the launch in the US and contributed significantly, with a growth of 14.7 billion yen. However, royalty revenue and others went down by 16 billion yen due to the drop in the sale of Gilenya. As a result, we saw revenue decline by 9 billion year-on-year to 424.7 billion yen.

FY2018 Business Results

Cost of Sales, SG&A Expense, Core Operating Profit

- **SG & A expenses reduced due to the operational productivity reform, etc.**
- **R&D expenses increased due to the progress of the late-stage global development.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	424.7	433.8	(9.0)	(2.1)	435.0	97.6
Cost of Sales	180.6	169.7	10.8	6.4	176.0	102.6
Sales cost ratio	42.5%	39.1%			40.5%	
Gross profit	244.1	264.1	(19.9)	(7.6)	259.0	94.3
SG&A expense	98.2	104.0	(5.8)	(5.6)	101.0	97.3
R&D expense	86.5	79.0	7.4	9.4	84.5	102.4
Amortization of intangible assets associated with products	2.9	2.4	0.4	19.7	3.0	97.8
Other income and expense*2	(0.5)	0.0	(0.6)	-	(0.5)	-
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8

※1: Announced on May 9, 2018 in the financial results of FY2017 ※2: Brackets indicate expense and loss.

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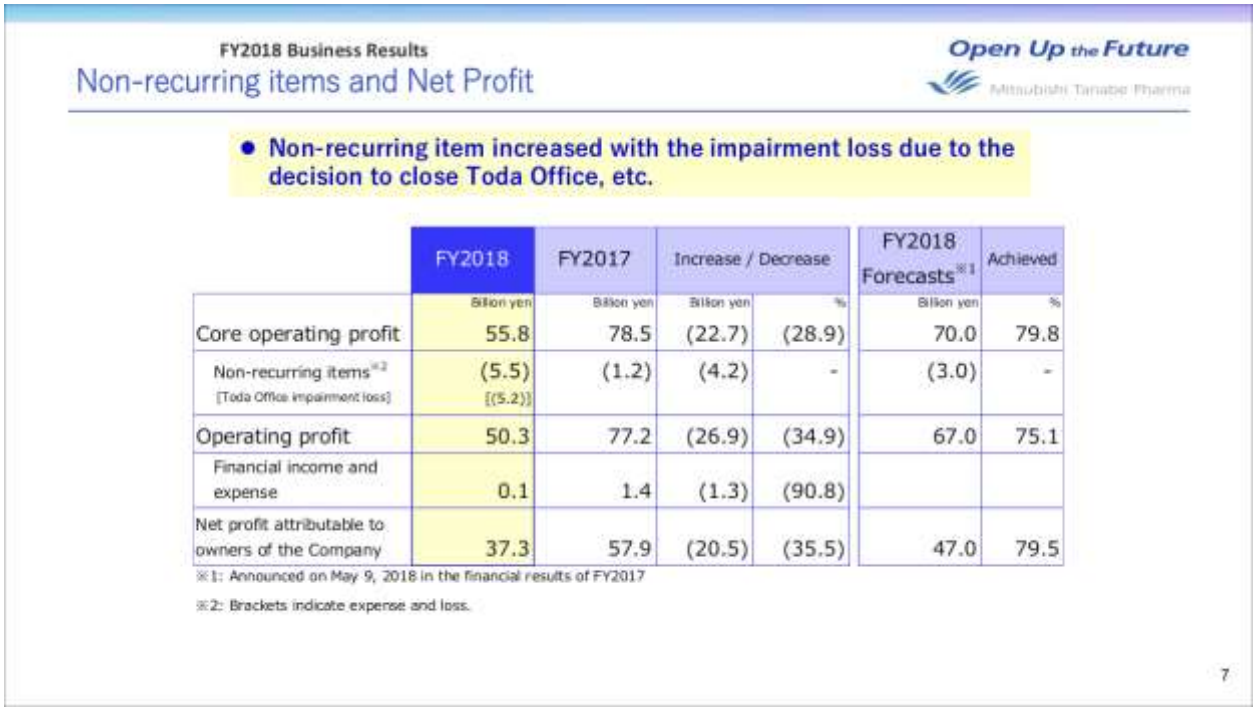
Let me now move to cost of sales, SG&A expenses, and core operating profit. Cost of sales increased by 10.8 billion, or 6.4%. Sales cost ratio was affected by the NHI drug price revisions, decline in royalty revenue, and changes in the product mix, resulting in the rise of 3.4 percentage points to 42.5%. SG&A expenses decreased by 5.8 billion yen, or 5.6%, to 98.2 billion yen due to the promotion of operational productivity improvement. R&D expenses went up by 7.4 billion yen, or 9.4%, to 86.5 billion, with the progress made in the late stage global development projects, such as ND0612 for Parkinson's disease and MT-2271, and influenza vaccine. As a result, the core operating profit totaled 55.8 billion yen, down 22.7 billion.



FY2018 Business Results

Non-recurring items and Net Profit

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- **Non-recurring item increased with the impairment loss due to the decision to close Toda Office, etc.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8
Non-recurring items※2 [Toda Office impairment loss]	(5.5) [(5.2)]	(1.2)	(4.2)	-	(3.0)	-
Operating profit	50.3	77.2	(26.9)	(34.9)	67.0	75.1
Financial income and expense	0.1	1.4	(1.3)	(90.8)		
Net profit attributable to owners of the Company	37.3	57.9	(20.5)	(35.5)	47.0	79.5

※1: Announced on May 9, 2018 in the financial results of FY2017

※2: Brackets indicate expense and loss.

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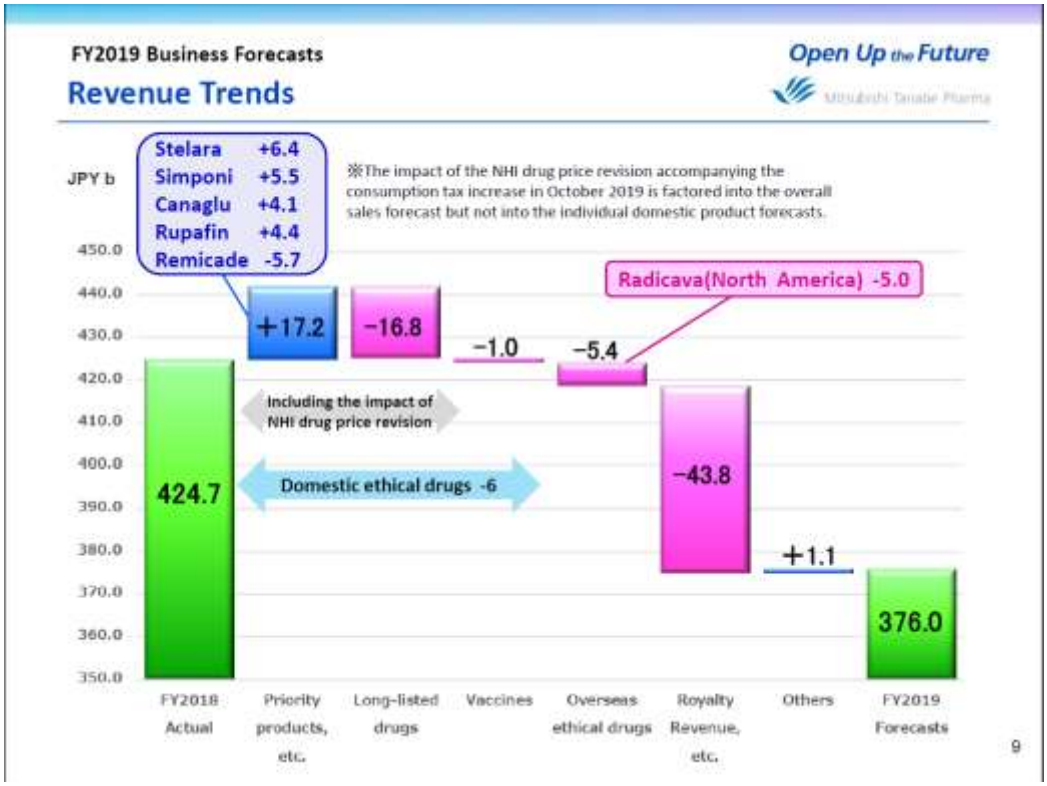
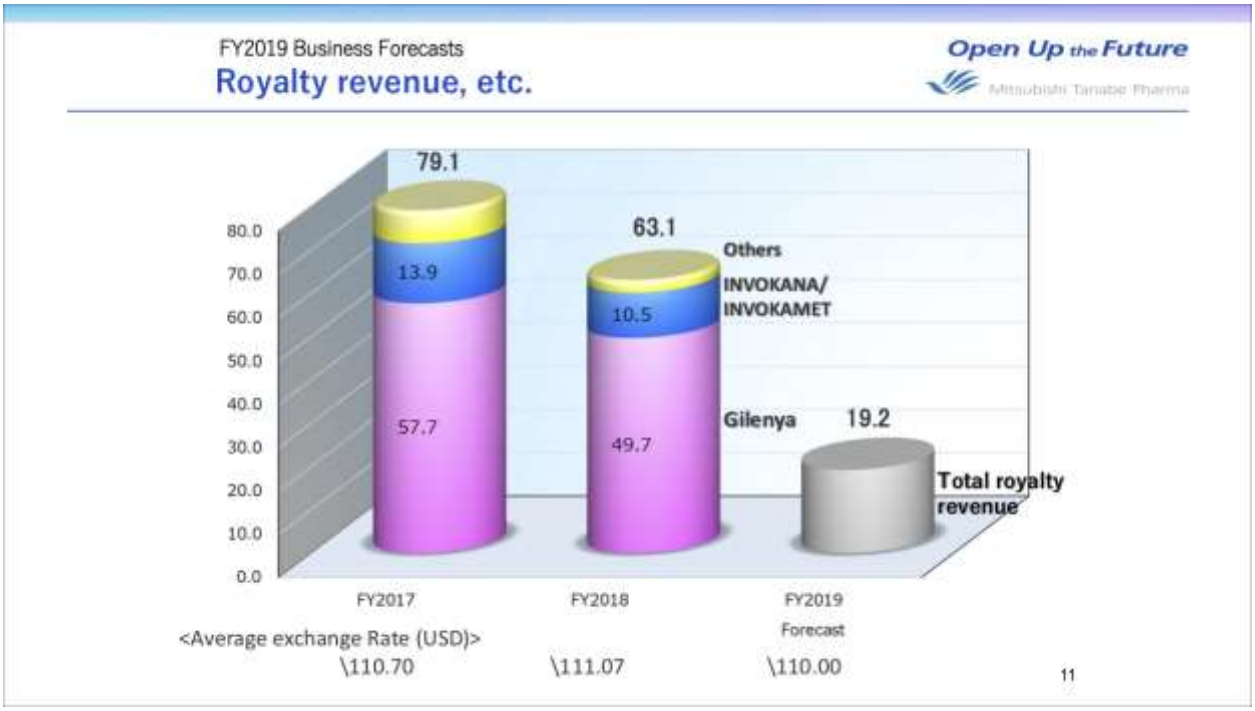
Next, as for nonrecurring items, mainly due to the impairment loss of 5.2 billion yen associated with the decision to close the Toda office, we saw the net expenses increase by 4.2 billion yen year-on-year. This led to operating profit of 50.3 billion yen, down 26.9 billion yen, or 34.9%. The financial income and expenses resulted in a net profit of 100 million yen. These have boiled down to the net profit attributable to owners of the company of 37.3 billion yen, down 20.5 billion yen, or 35.5%. Let me now move on to the forecast of fiscal 2019.

In revenue of domestic ethical drugs, we will work to offset the impact from the revisions of NHI drug prices accompanying the consumption tax hike scheduled in October 2019 by growing the priority products. On the other hand, with regard to the Gilenya royalty income, as we expect to be still in the arbitration proceedings with Novartis Pharma, we have decided not to recognize some of those amounts as our revenue. Therefore, we expect the total revenue to be 376 billion yen, down 48.7 billion, or 11.5% year-on-year. The core operating profit is forecast to see a significant decline of 45.8 billion, or 82.1%, to post 10 billion yen.

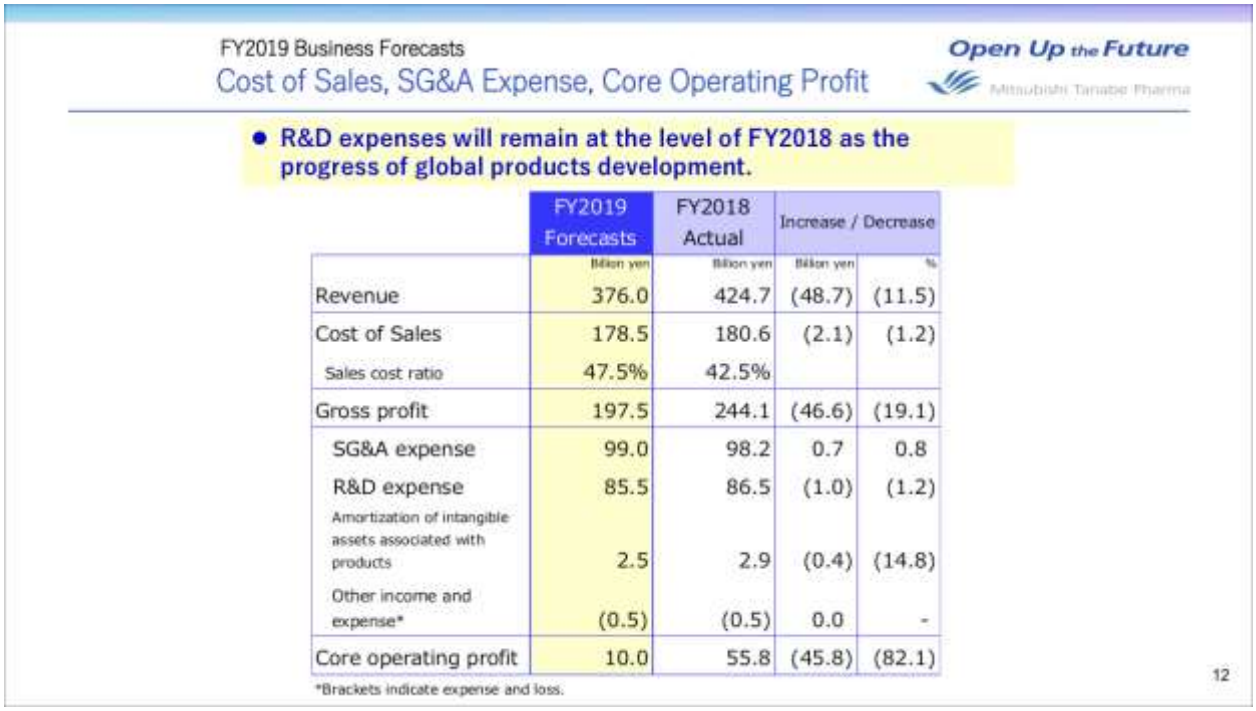
As for nonrecurring items, we expect to post a gain of 1.5 billion yen on planned asset disposition and consequently, the operating profit is forecast to fall by 38.8 billion yen, or 77.1%, to 11.5 billion yen. As a result, net profit attributable to owners of the company is expected to be 5 billion yen, down 32.3 billion yen, or 86.6% year-on-year.



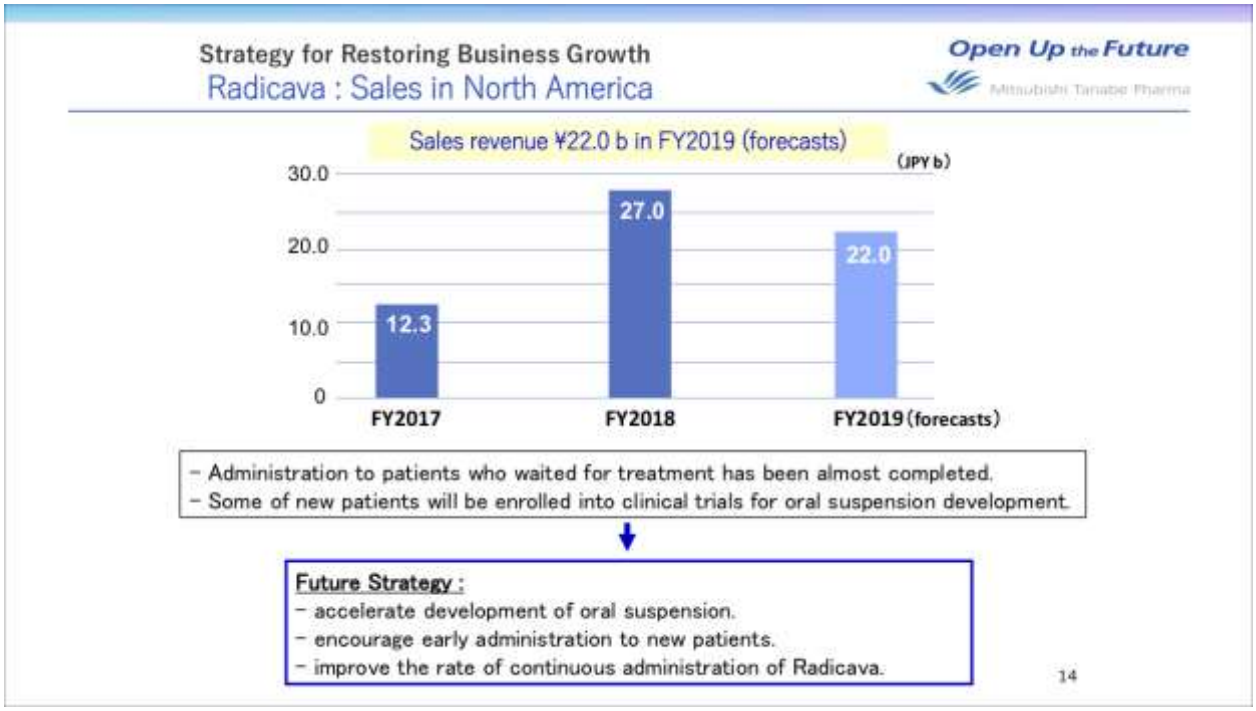
Let me now explain about the factors behind the changes in revenue. In the domestic priority products, while we expect to see growth for Stelara, Simponi, Canaglu, and Rupafin, we're factoring in a decline in the revenue of long-term listed products and impact of NHI drug price revision accompanying the consumption tax increase in October 2019 to some extent. Therefore, total domestic ethical drugs are expected to post a negative growth of 600 million yen. As for overseas ethical drugs, Radicava in North America is expected to post 22 billion yen, down 5 billion yen year-on-year, while royalty revenue and others are expected to go down by 43.8 billion yen from a year before. Consequently, the revenue is forecast to post 376 billion yen, down 48.7 billion yen year-on-year.



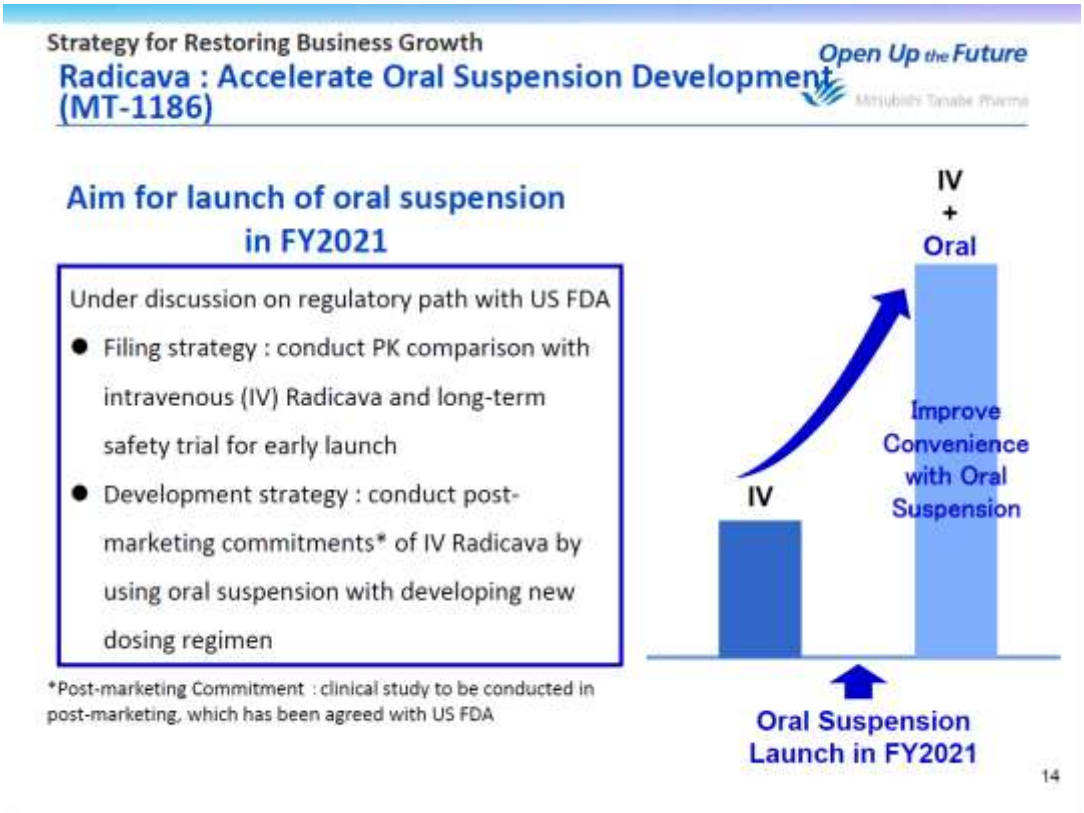
The royalty revenue is as shown on this slide. In fiscal 2019, the royalty revenue is expected to go down by 43.8 billion yen, to 19.2 billion yen.



Next, I will explain about the cost of sales, SG&A expenses, and core operating profit. Cost of sales is forecast to decline by 2.1 billion yen, or 1.2% year-on-year. SG&A expenses are expected to increase by 700 million yen, or 0.8%, to 99 billion yen. And R&D expenses go down by 1 billion yen, or 1.2%, to 85.5 billion yen, which would be about the same level as fiscal 2018. Consequently, the core operating profit is expected to post 10 billion yen, down 45.8 billion yen. Next, I'd like to discuss our approach to restore the business growth, and our thoughts behind this.



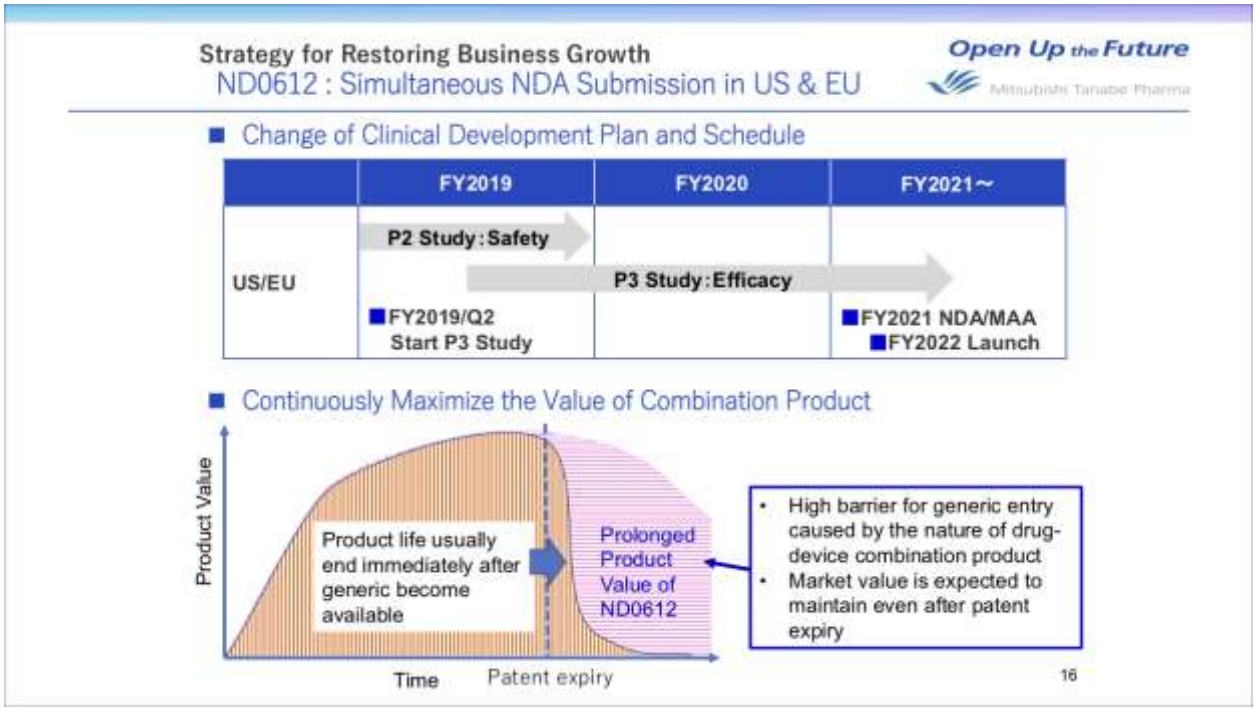
The first one, Radicava. In North America, the sales revenue grew significantly, by 14.7 billion yen year-on-year in fiscal 2018, to record 27 billion yen. But in fiscal 2019, it is anticipated to post 22 billion yen. This is primarily because: A, administration to patients who had been waiting for the launch has been almost completed, and B, some of the new patients are being enrolled into our clinical trials for oral suspension development in the second half of this fiscal year.



Going forward, we will work to accelerate development of oral suspension and encourage early administration to new patients and improve the rate of continuous administration of Radicava. We will accelerate the development for oral suspension formulation, which is more convenient than IV, in order to maximize the product value of Radicava, which is scheduled to be launched in FY2021.

We are currently in negotiation with FDA regarding the submission package, including two pivotal studies. One is a PK comparison versus IV, and the other is a long-term safety for oral suspension.

We plan to implement the post-marketing commitments which were given at the time of IV approval two years ago in oral suspension. Specifically, removal of two weeks of drug holiday and doubling of the doses. So, these obligations will be implemented in oral suspension, so that we can study new dosage measurement and also, at the same time, pursue convenience.



We have formulated the Phase 3 study plan, based on FDA's advice for Parkinson's disease treatment, NeuroDerm, ND0612. Study is to begin in the second quarter for this year and it should take approximately two years for simultaneous submission in US and Europe in FY2021 and launch in FY2022.

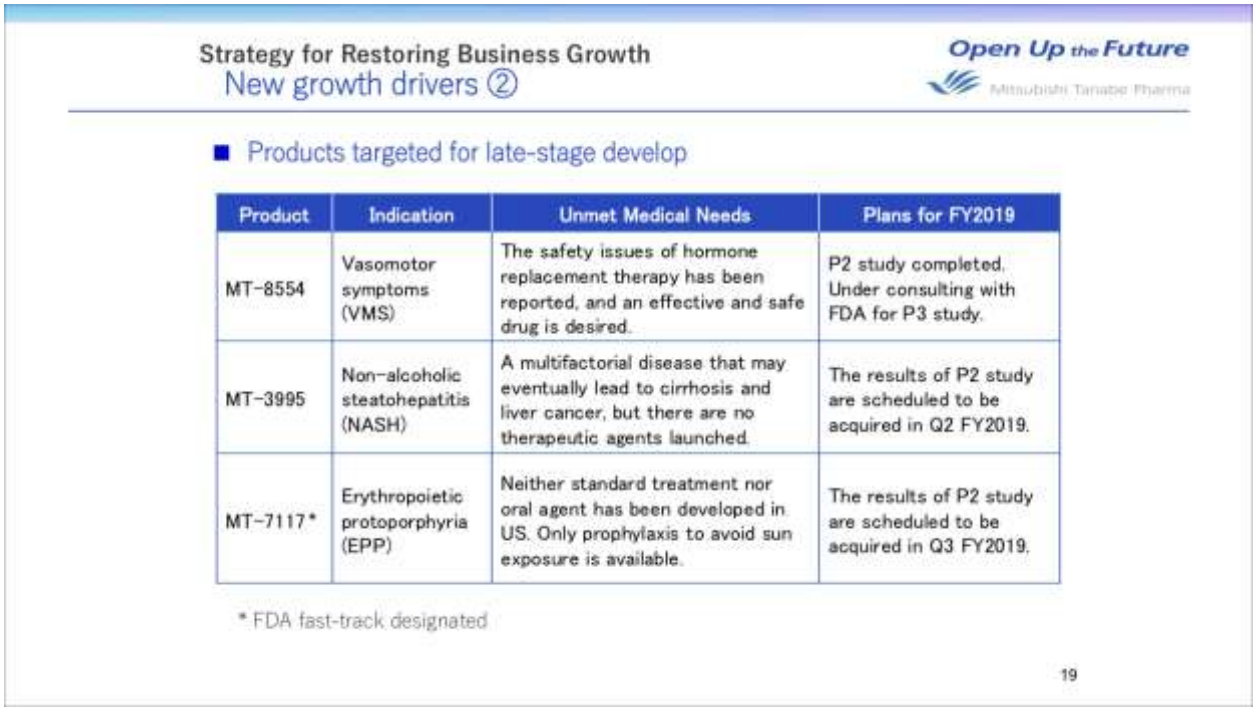
ND0612 has been developed as a combination of IV solution as well as an injection pump for optimized administration. Normally, at patent expiry generic would enter and the product life expires quickly. But, with a combination product, the device can be continuously improved, increasing added value and convenience. Therefore, we expect the market value of this product to continue to be sustained, even after patent expiry.

I would like to explain about MT-2271, Medicago, seasonal influenza plant-based VLP vaccine. This is unique because we can expect quicker manufacturing and no egg adaptation.

In North America, our peak share target is 10%. And we will be building and investing into capacity of 20 million doses in the new plant in Québec, to be operational in FY2023. Phase 3 in adults has been completed. We are currently in consultation in preparation for filing with FDA. Now, FDA has requested to see data from the Phase 3 study in the elderly, which should have a readout in the second quarter of this year, and the study was conducted in last winter season. Therefore, we will be filing submission before the end of this fiscal year, not only for elderly but also adult indication. Similarly, in Canada, we plan to file before the end of this fiscal year.

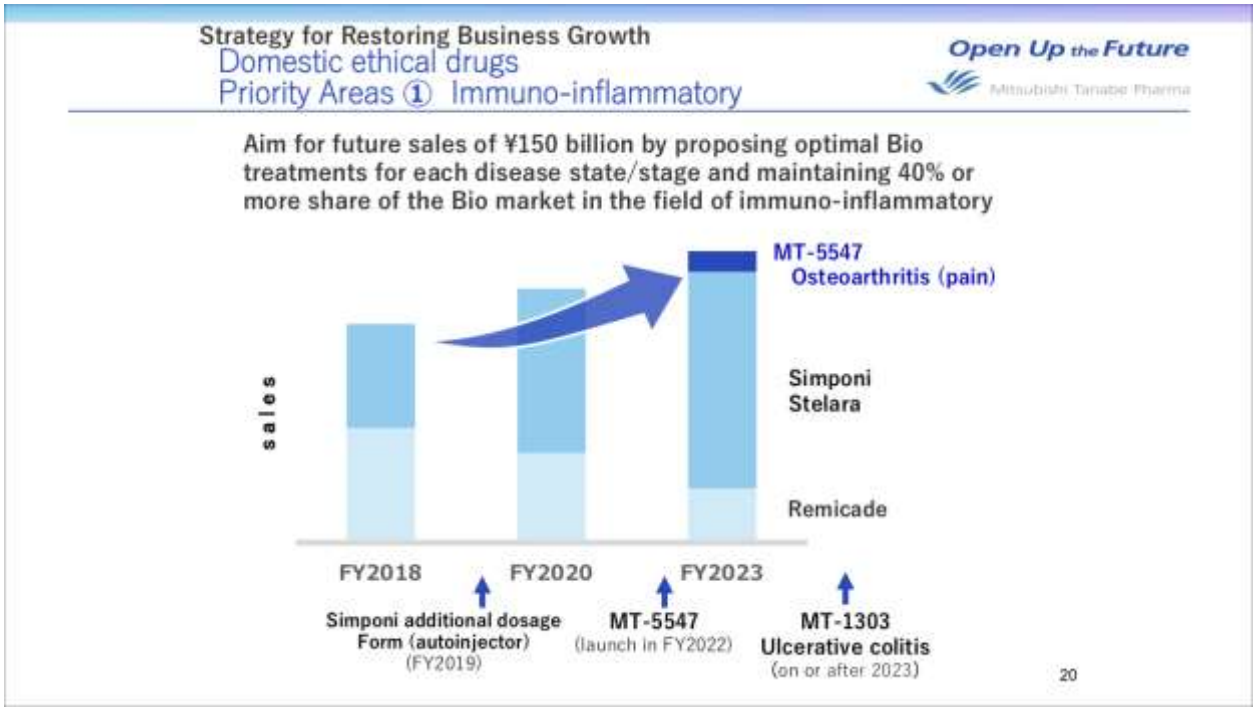
Next, I would like to talk about products with potential growth driver. We have concluded a license agreement with Bausch Health in April for MT-1303.

Salix, which is dedicated to GI disease and a subsidiary of Bausch Health will implement global development in ulcerative colitis. We own the rights for filing and marketing in Japan and parts of Asia using the results of this global clinical trial. We will also be actively involved in global development on our own in neurology, as well as rheumatology, where we reserve the rights.



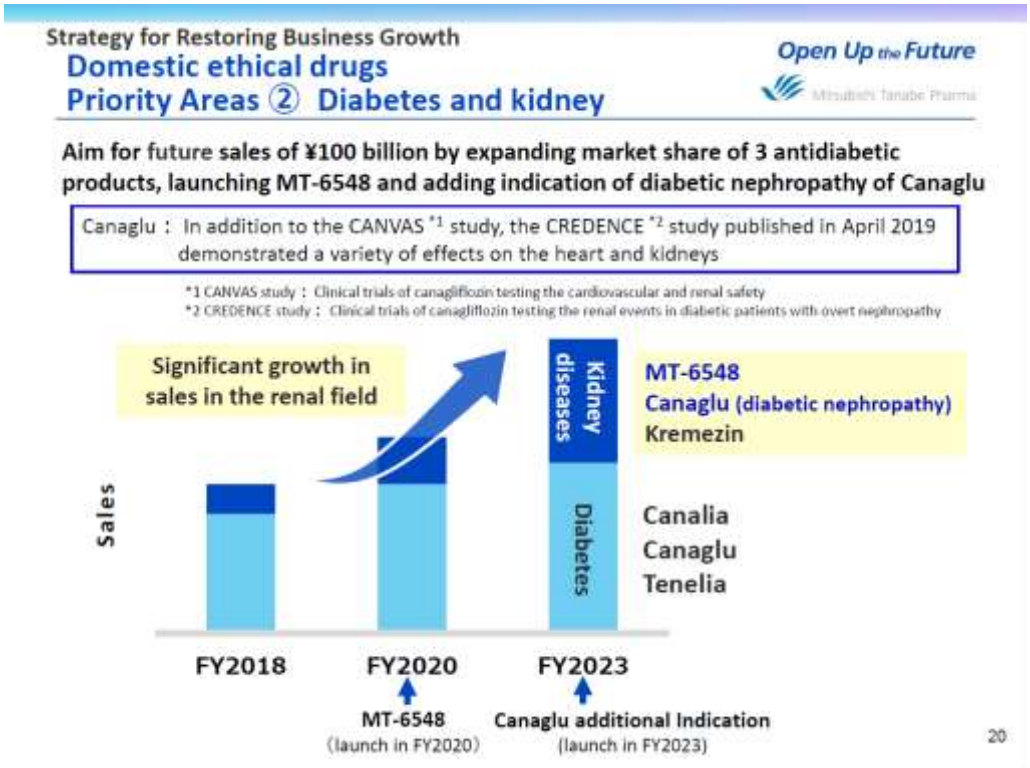
On this slide, you can see some additional product targeted for late-stage development in this term. For MT-8554, we completed Phase 2 study, and we are preparing FDA consultation for Phase 3.

MT-3995-- POC results are expected in the second quarter of this year, and for MT-7117, in this third quarter. Studies are going smoothly according to this plan. MT-7117 has been designated for fast track by FDA. Therefore, we want to put this in the late-stage development as soon as possible.



Moving on to domestic ethical drugs, starting with the immunoinflammatory area. We are the only manufacturer dealing with three bio products: Stelara, Simponi, and Remicade. And we continue to propose the best possible treatment for each stage and status of the patient. For Stelara, we want to establish the position as first bio in GI and IBD by telling the story of sustained remission, low immunogenicity, and safety.

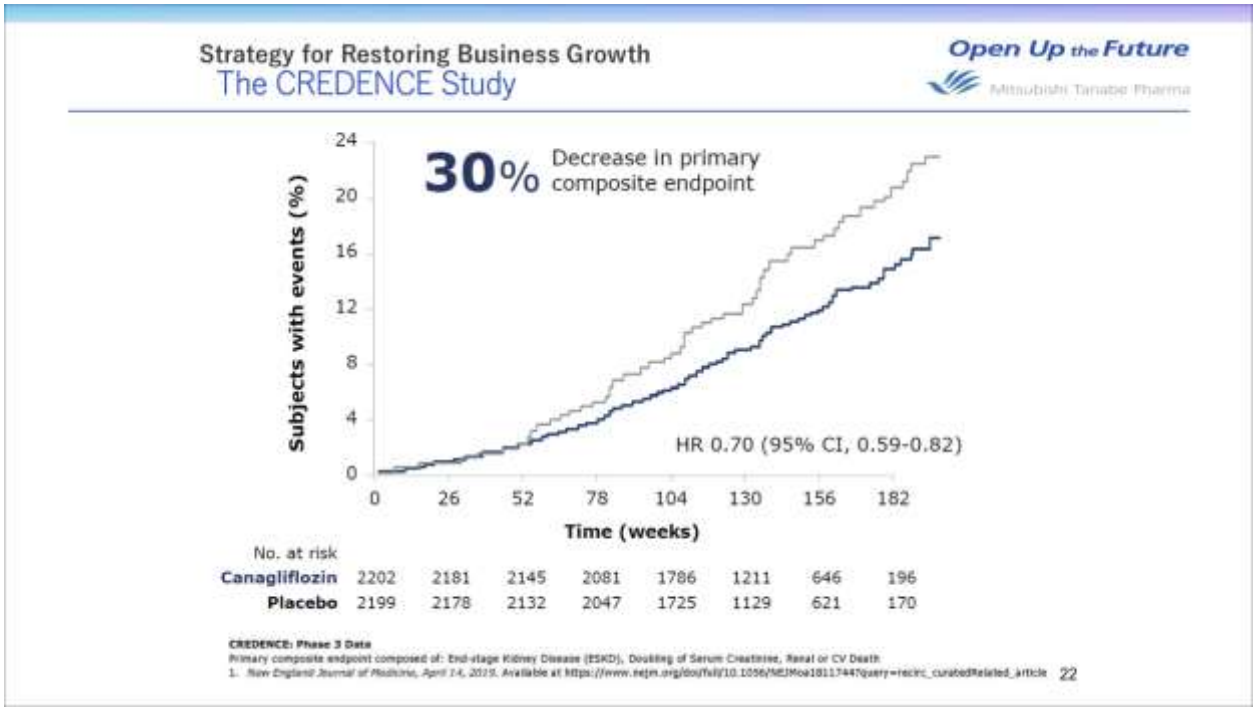
For Simponi, prescription for elderly rheumatism is increasing and the number of patients for self-injection is also increasing. This year, we intend to launch autoinjector, which will help further permeation into the market. In relation to these bio products, your currently developing anti-NGF antibody MT-5547,Fasinumab, for osteoarthritis. By launching this product, we want to maintain the bio share of above 40% and achieve 150 billion yen in sales in the future. As explained before, although the development plan is not confirmed, we want to launch MT-1303 in Japanese market for ulcerative colitis, so that we can further expand our business in the immunoinflammatory area.



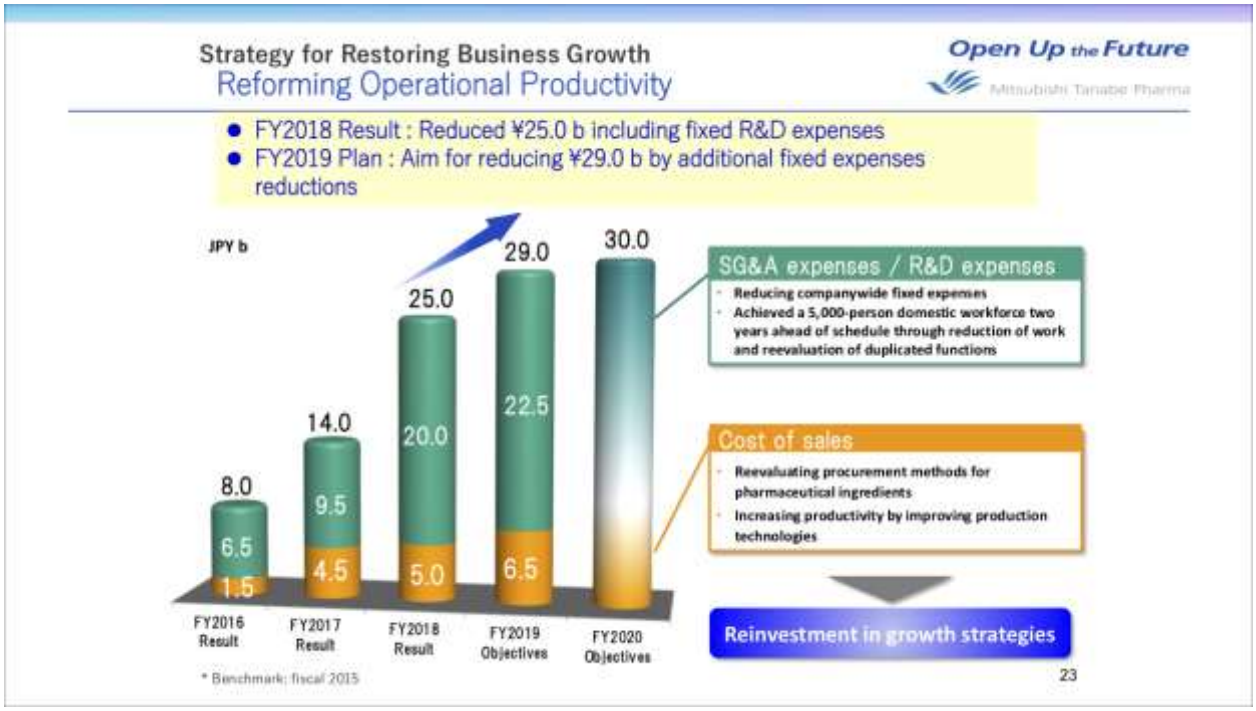
Moving on to diabetes and kidney, we will continue to expand the market share for Canalia, Canaglu, and Tenelia. Canalia's market share grew to 10% after 18 months from launch in the SGLT2 inhibitor market. The market continues to expand, and we want to see sustained growth of this product as a number one combination product.

For Canaglu, in addition to CANVAS, as will be explained in the later slides, this April, the results of our CREDENCE study have been announced, demonstrating various effectiveness for cardiac and renal functions. We will continue to contribute to the treatment of diabetic patients through information provision of appropriate evidence.

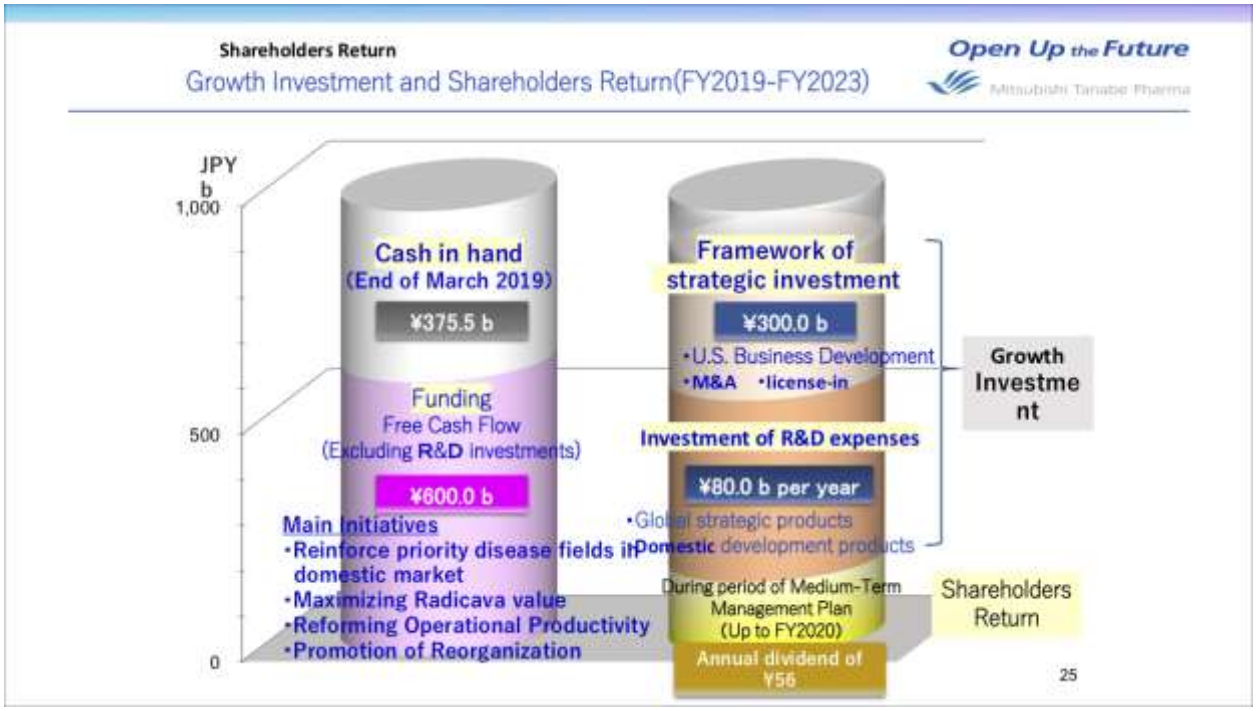
Now, renal area is a focus area. Here, we have Kremezin, and we plan to launch MT-6548, Vadadustat, and conduct line extension for Canaglu for diabetic nephropathy. We will continue to increase the sales in the renal in addition to the diabetes so that we can achieve 100 billion yen in sales in the future.



Just for your reference, I would like to refer to the readout of the CREDENCE study. On the 15th of April, in Melbourne, at ISN WCN, Janssen presented the results of our CREDENCE study which was a global study, including Japan and Asia. In primary composite endpoint, canagliflozin showed a 30% risk reduction against placebo. This is great data and also great news for many patients who are suffering from CKD complicated with type II diabetes.



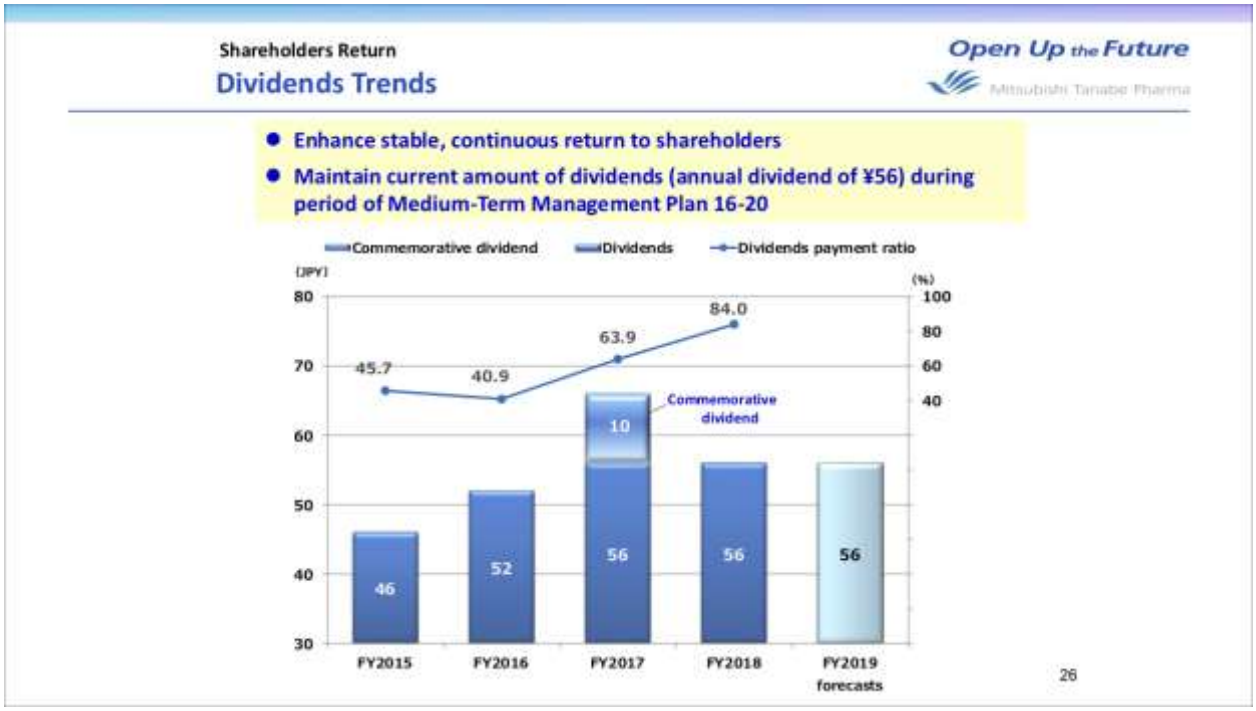
Next, I would like to explain about our operational productivity reform. We have seen study results from this initiative. And in 2018, compared to FY2015, we achieved a savings of 25 billion yen. And 5,000 people in Japan, this target was achieved two years earlier at the end of 2018. In FY2019 we will continue to promote the initiatives so that we can save 29 billion as compared to FY2015, and also frontload the achievement of a saving of 30 billion yen by FY2020.



Lastly, the fourth item, about the shareholder return. As I mentioned in the outset, during the arbitration period for Gilenya, the royalty revenue cannot be recognized, which will have a big impact on our performance and P&L. However, at the conclusion of arbitration, depending on the outcome, the number will be recognized as a whole, in one go. And therefore, for the midterm, we do not expect a major impact. And therefore, we believe we are on track, according to the midterm management plan, which was revised last November. Therefore, no major changes have been implemented against the current plan for the achievement of the target in FY2023. We will continue to pursue these plans.

Our current plan includes strengthening immunoinflammatory area, diabetes and kidney for Radicava, accelerate the oral development, and also accelerate the development of late stage projects. In order to strengthen our business domestically, we will continue to improve the operational productivity and reorganize some sites. And by FY2023, we wish to generate cash worth approximately 600 billion yen.

On the other hand, we will continue to invest into R&D, mostly centering around global development, and this is approximately 80 billion yen per year. And we also have allocated strategic investment worth 300 billion yen in order to capture opportunities for M&A and in licensing. And the balance between right and left should generate shareholder return. We want to achieve concrete results so that we can achieve the first set of targets, 500 billion yen of sales and 100 billion yen core operating income by FY2023, so that we can ensure future leap and growth. And our shareholder return policy remains the same at 56 yen per share, up until FY2020, as we announced last November.



So, as I have just explained, in terms of dividend, we will maintain the annual dividend of 56 yen for this period, based on the revised midterm management plan, which was announced last November.

That's all from me. Thank you very much for your kind attention.

Question & Answer

Analyst1: There are several questions. My first question is about how to look at the forecast. How certain are you about the timing of when the arbitration proceedings, with regard to Gilenya royalty, will be finished? If my understanding is correct, if you are expected to be finished by the end of this fiscal year, you could have included the original forecast of royalty revenue in this forecast. But this is the level of forecast that you came up with and that means that it is highly likely that the proceedings will not be finished by the end of this fiscal year. So, can you give us your prospect at this moment?

Tabaru: With regard to arbitration proceedings, based on the advice from lawyers, we were told to refrain from making any specific comments on arbitration proceedings. And, with regard to duration of the proceedings, we don't have any prospect and we don't know if this will be finished by the end of the fiscal year or next fiscal year.

Analyst1: With regard to the expenses, you said that this is within the range of the midterm plan. I understand that you're not in the situation where, due to this level of profitability, you need to reduce expenses, correct? If this is the level of profitability that you will continue to see, then is there any possibility to fundamentally review the management policy, including how to spend your expenses?

Mitsuka: At this moment, our position is that we are in a position to receive royalty revenue that we are entitled to under licensing agreement with Novartis Pharma. And also, if you look at the clauses in the contract objectively, we don't believe that the projects or development projects and investment plans need to be reviewed, and there are projects in Phase 3 or right before filing, or projects to be brought to Phase 3. If we apply the brakes on any of these, that would undermine the corporate value of the company.

Analyst1: And if the 10-billion-yen profitability continues, what would happen?

Mitsuka: Well, our position is that we are entitled to receive the royalty revenue. So, we are not in a position to answer any hypothetical questions.

Analyst1: Now, my question about MT-8554. Astellas Pharma has already published data in academic congress, and they seem to be in negotiation with authority prior to Phase 3. And you also made progress in data analysis. Can you tell us how you look at this product and its competitive advantage? And do you think you can move to Phase 3 at the same time as Astellas? And if you can have any updates on partnership, if you can share that with us, that would be appreciated.

Kobayashi: As you can see in page 18, based on the results of Phase 2, we are now in the process of consulting with FDA for the next phase. And once we have the proper results from that consultation, we think we should share that information with you. With regard to partnering, it is a fact that we are looking for partners. But, if we stop our development activities until we find a partner, then that would be a great loss. So, we would like to move along with the development, while looking for partners.

Analyst1: My last question is about MT-2990. This was not explained. But, in the supplementary data, it said that it is in Phase 2 for endometriosis. With IL-33 antibody, what is the concept behind the target indication of endometriosis? Previously, in the disclosure, it was said to be targeting at inflammatory and autoimmune diseases. Is there any possibility to expand the indications to others?

Kobayashi: IL-33 is a multifaceted multifunctional cytokine. And it is known that it will promote proliferation of lesions and pain in endometriosis. So, by blocking IL-33, we will be able to treat endometriosis and we

started to obtain POC for that. And there are still high unmet needs in endometriosis. That's why we chose this indication.

Analyst1: What about other indications?

Kobayashi: We will continue to look at other indications, such as seasonal allergic rhinitis. So, we will continue to look at other indications as well.

Analyst1: Thank you.

Analyst2: My first question has to do with not so much about arbitration, but the Gilenya royalty. So before, you explained that we would see a decline in the royalty rate to some extent. So, if you were to provide a performance forecast, I know that the rate reduction is not really disclosed. But, even if the payment came through, it would just offset the decline of the rate of royalty. Is that the extent?

Tabaru: This year, in August, the patent will expire, which means that the patent rate would go down. And therefore, there is a step down expected and that's what we explained for FY2019.

Analyst2: I understand. In terms of cash flow, the payment is still continuously coming from Novartis. I don't know about the timing. Maybe once several months. But, if we look at the cash flow, do we know how much money is coming in from Novartis?

Tabaru: As far as the payment is concerned, it concerns our agreement. Therefore, I cannot really provide you with an answer. But, the amount for the third quarter did come in.

Analyst2: I see. So, it's not recognized on IFRS, but cash wise it's coming in?

Tabaru: Yes. Part of the third quarter payment was considered legal by them. So, it has been paid. But, for the fourth quarter, we are still waiting.

Analyst2: Thank you. Second question, regarding oral suspension Radicava, to be launched in FY2021 and filing scheduled for FY2020. I think that's the current situation. And I can see the data on the slides. But if you compare this midterm management plan versus the previous plan, there were some delays of development of projects, especially overseas. And that's probably some of the learning points from the previous plan. What about this midterm management plan? Maybe you expect something with FDA. But, technically speaking, do you expect any delays, by one or two years? I don't think you can deny the possibility altogether.

Kobayashi: You can see the information on page 14. And, yes, it's true. That issue occurred with several programs. But currently, more or less everything is going according to schedule.

Analyst2: I understand. The last question, about the overseas sales of Radicava. When the clinical trial starts, I know that for rare disease patients tend to go to clinical trials and it's taken away from other programs. But I understand that development is going on in Canada and Switzerland in Europe. Even including those numbers, do you expect a decline in the number of patients? I think this a major decline in the number of patients. Is this just a one-off situation to be recovered in the future? Or do you think the situation will continue further?

Mitsuka: To be quite candid, we have not really planned for FY2021, which is the following year. So, we know the current trend, how many are enrolled in the clinical trials, and how many patients we are losing or gaining every month. And, based on those numbers, as a total, we have this unfortunate result for FY2019. And you cannot really see the details on the slides, but we want to encourage early administration for new patients and also improve the nursing care to stop dropouts. We will make efforts this year and if these efforts turn out to be effective, hopefully we can see better numbers for next year.

The biggest challenge of Radicava is that administration is very cumbersome. This is a daily infusion over two weeks, which is challenging, and also, we have not conducted any clinical trials in the US, meaning lack of evidence in the US and this is a voice that we hear from the clinical practice. So, through development of oral suspension, we want to address the problem of convenience, and also at the same time, as you can see on the next page, we can use it as a safety study, Phase 3 study for direct approval. So, originally, we were requested to collect more data for P4. That was a commitment. And by combining these two, we believe that we can accumulate a lot of evidence in the West. So, we have decided to focus on this, although it may seem it will take longer.

Analyst3: Thank you for the presentation. My first question is about tax rate. Superficially, in this fiscal year, tax rate appears to be quite high. So, how should we look at the tax rate or the effective tax rate for the next fiscal year onward?

Tabaru: The tax rate has been heightened, because first of all, the profit of the company on an unconsolidated basis has declined significantly and the percentage of mid 20s, or ordinary tax rate is applied to that portion. But as for NeuroDerm and Medicago businesses, we have not accounted for tax effect. So, the weight of those businesses has increased, relative to the total. So, as a tax rate, it has jumped up.

Analyst3: Thank you. My next question is about vaccine capex. 13.5 billion yen has been recorded for this fiscal year. How long do you think this will continue?

Mitsuka: Can you move to the next question? We'll answer that question later.

Analyst3: My next question is about dividend policy. During the midterm plan period, you said you're going to maintain the current level. But, if Gilenya royalty revenue remains unable to be recognized after fiscal 2021 as well, how are you going to look at dividend policy?

Tabaru: In November last year, in the midterm plan, we said that in fiscal 2020, 56 yen per share will be maintained. After FY2021, we don't know if the situation will remain the same. But looking at the situation, we will have to make decisions.

Analyst3: So, at this moment, you don't have any prospect to share with us?

Tabaru: No. We don't have the prospect that has been decided yet.

Mitsuka: Getting back to the previous question, about the plant in Québec, total capex is going to be about 25 billion yen. And in fiscal 2018, last fiscal year, 1.8 billion yen was spent. And in fiscal 2019, if everything goes as scheduled, 13.5 billion yen is expected.

Analyst4: I have a question about Gilenya royalty. How do you think it's going to be concluded? Do you expect conclusion in one go? I understand that there are points of dispute for part of the contract or agreement. Are we talking about multiple items or categories? For example, do you have point of dispute for pediatric patent and then another point of dispute for dosage and administration? And therefore, the conclusion of the arbitration may come in two stages? Or is that not a possibility? That's my first question.

Mitsuka: We cannot really comment on how many points of dispute we have and the expression, "a part of" may be a little bit confusing in the Japanese translation. But this was taken from the wording that our attorney used, and it was translated. Our understanding is that arbitration will be concluded in one go and basically, all of the issues will be cleared at the same time.

Analyst4: I understand that you have best scenario versus a worse scenario. What about a possibility of reaching a settlement, agreeing on a settlement which is between the best- and worst-case scenarios?

Mitsuka: At this point in time, since we are talking about a large number, we believe that the possibility of reaching a settlement would be very low. In other words, our position is that we should assert everything we can.

Analyst4: Thank you. Next question relates to Medicago. According to the guidance, the noncontrolling equity for the first half, it's plus 3billion yen and for the full year, it's minus 1billion yen and so on and so forth. Can you please explain the mechanism of this?

Tabaru: There are two factors behind this. One is cost generated within Medicago. For the elderly, this has basically been completed. So, this should improve the profit. And some of that positive impact is transferred to the partner. And also, there is an intergroup transaction, and that pushes up Medicago's profit for the second half. And again, the partner benefits from this. So, in terms of equity pickup, our number will be a little bit lower.

Analyst4: So, intergroup transaction, is this some kind of milestone payment, paid by your company to be posted for influenza filing?

Tabaru: Well, once the decision is made, we can provide you with explanation. But this is related to the influenza vaccine in the US.

Analyst4: My last question: How much cash do you have with MCHC. I cannot really tell that from the balance sheet or the financial summary. So, how much do you have with them?

Tabaru: It's approximately 100 billion yen.

Analyst4: Thank you very much.

Analyst5: Thank you for the presentation. My first question is about Radicava. I understand your sales plan, but in the last fiscal year, when the growth of the number of patients for Radicava started to slow down, you took some initiatives, like J code assignment and home healthcare focus. Was that effective? And, with regard to Europe, you said that in Europe and US, no clinical trials have been done, so if that is the case, then even if you get approval with the data not obtained in Europe, you don't expect this product to be selling so well. Is that correct?

Tabaru: With regards to initiatives, we came up with the concept of 3P's and explained about that. The first "P" is payers, and with regard to the reimbursement, we have been proactively explaining to the payers, so that they will not stop reimbursement in the middle of the treatment. It actually proved effective. And, in January this year, J code was certified. So, in terms of reimbursement procedures, on the hospital side, it was simplified. So, it was effective. And, with regard to patients, the copayment service program was changed to more simplified cards. And this did have some number of users. And so, there was some effect that we've seen to some extent. But if you ask us if there was any dramatic effect, no. Not that much.

And with regard to home healthcare nurse services, we are increasing the number of personnel, and this has been positive. But not as much as we had expected.

With regard to physicians, to the hospitals with a large number of patients, our president and other top management members went over and talked to them and there were more hospitals that started to use Radicava because of these visits, so this was effective. But in total, we have about 200 million dollars in sales and all these factors are included. And as a result, we had this number of sales.

Mitsuka: With regard to Europe, I'd like to just share with you our thoughts on the quantitative basis. If you talk to various physicians, some would say that suppressing the pathological progression with the current data would be enough while other physicians may say that you need to have hard endpoint or mortality and other event data. So, even if approval is acquired, with the J19 data, would that be convincing enough? It may be difficult. And also, based on the market research, we found that the oral suspension is much higher demand than we had expected, in Europe, much more than in the US. In any case, ultimately, we need to get approval for oral suspension. Otherwise, the business in Europe would not be big enough to support our business. That's our current understanding.

Analyst5: Thank you. My second question is about MT-2271. There was data for adults. And you said you were in consultation with FDA. But, in today's presentation, you said that FDA now wants to check the data on elderly patients in Phase 3. So, what were the factors behind the changes in your thinking in FDA, that they want to check the elderly data now?

Kobayashi: Well, we have been taking stepwise approach, first for adults, and then elderly patients and pediatric patients. And we were in the middle of consultation with FDA, first on adult data. But then, FDA said that if elderly patients' data would become available soon, then why don't we have discussion on both the elderly and adult data, because that would be more efficient.

Analyst5: So, the adult data alone would be insufficient to back the filing for approval because it seemed to be negative.

Kobayashi: No. We can't comment on details of the negotiation with the FDA. But they said that we could have more, better discussion with two trials together.

Analyst5: My last question is about MT-8554. Consultation for Phase 3 is about to start. Phase 2 study was completed. I understand that it must've been successful. When do we see the Phase 2 data for MT-8554, and when will you disclose the mechanism of action? I have looked at the patents and I have some idea about MoA, but when do you intend to disclose the information?

Kobayashi: We would like to do that as soon as possible. If possible, before the end of FY2019.

Analyst5: Would it take the form of presentation at a congress?

Kobayashi: Yes. The first disclosure of the clinical outcome should take place at a congress.

Analyst5: I understand. Thank you.

Analyst6: I have two questions, and another question about cash flow of Gilenya. I want to clarify something about the answer that you gave. So, royalty rate was expected to go down in FY2019, according to your guidance. And the reason was substance patent would expire in February 2019. And with pediatric, you had a six-month extension, but the rate would go down afterwards. Now, Novartis has its own patent for dosage and administration, which was actually supported by the patent office in the US. Regarding this point, or overall, do we see some kind of cash flow coming in from Novartis for this fiscal year?

Tabaru: The details are actually in the agreement and according to our previous explanation, expiry in August and after that the royalty revenue would remain at a certain degree. But this is based on sales by Novartis. And since it is based on sales, we assumed that there would be no impact of the dosage and administration patent being supported. But Novartis is refusing to pay.

Analyst6: And they are refusing to pay the royalty based on the sales? Is that the amount that they believe they don't have to pay to you? And, if that is the case, you cannot really expect cash coming in after August, and that is the investors' assessment. How do you respond to this question?

Tabaru: It relates to the details of arbitration. So, I would like to refrain from answering this question.

Analyst6: Thank you. Next question is about Vadadustat. FibroGen, on Friday in the US, presented the data for dialysis. And the data itself was not really clear. I understand. But the way the FDA evaluates versus how EMA does it seems to be different. So, how do you see this data? What is your point of view? I'm really wishing that a similar thing will not happen in Japan.

Kobayashi: I have not really seen all the details. I have just seen the news. But in terms of MACE event, we wanted to show the advantage. But it was basically non-inferior and not superior. I think that was the essence. However, we have no access to the full FibroGen data. And at this point in time we do believe that the data is good enough for submission. But, if we want to add more value to the data package, actually we are conducting our own MACE studies. So, this is how we could potentially add value.

Analyst7: Just one question about Gilenya. Do you think there's going to be an impact on the sales of Imusera within Japan?

Kawakami: We do not expect any impact within Japan.

Analyst7: So, Novartis is not going to stop selling Gilenya?

Kawakami: That's correct.

[END]

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Document Notes

1. This document has been transcribed based on simultaneous interpretation.