Mitsubishi Tanabe Pharma Corporation

Q3 FY2018 Business Results (April-December, 2018)

February 4, 2019

Event Summary

[Company Name]	Mitsubishi Tanabe Pharma Corporation
[Event Type]	Earnings Announcement
[Event Name]	Q3 FY2018 Business Results (April-December, 2018)
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[Date]	February 4, 2019
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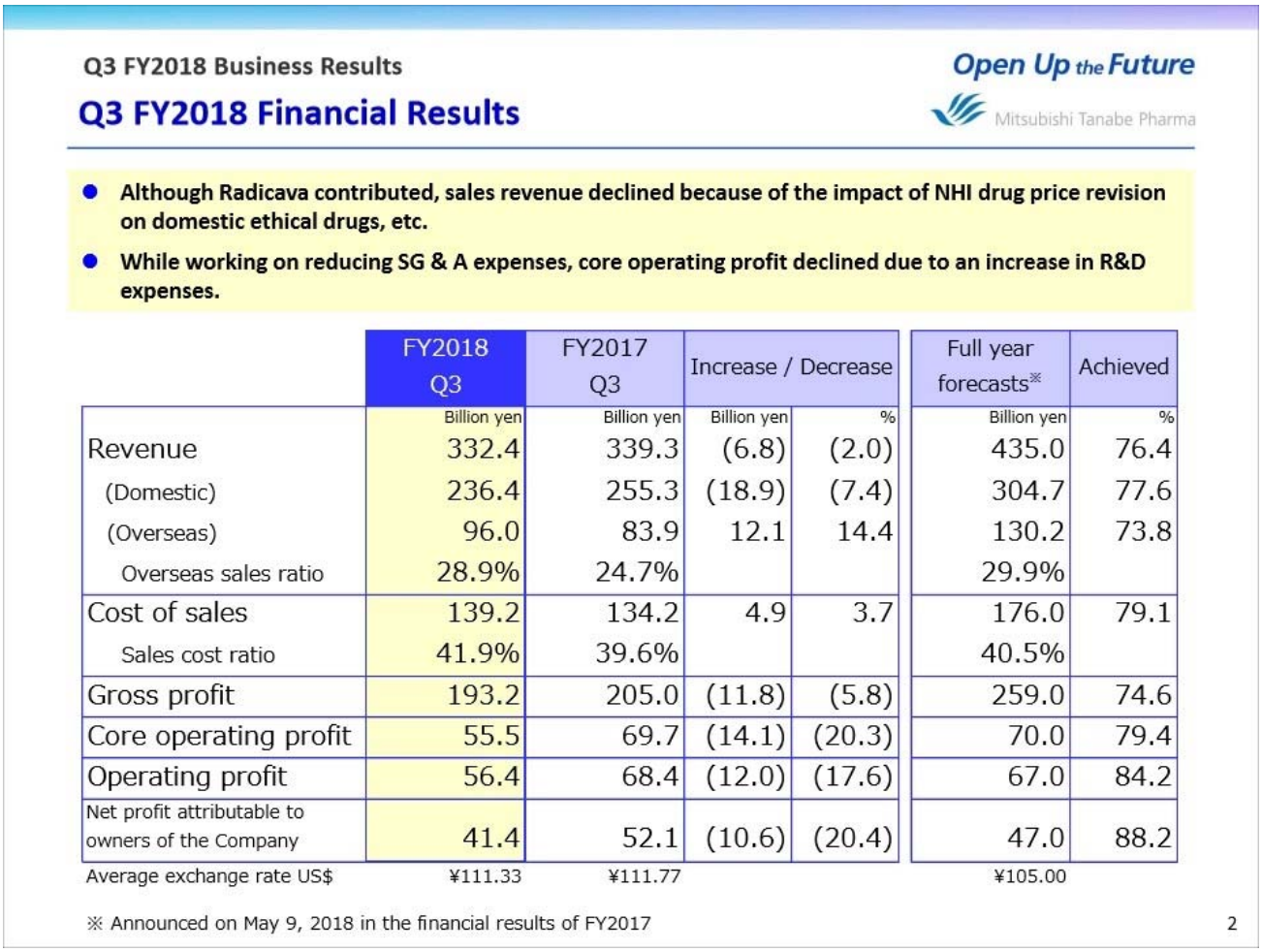
[Venue Size]	
[Participants]	approximately 60
[Number of Speakers]	3

Eizo Tabaru	Member of the Board, Managing Executive Officer
Yoshihiro Kobayashi	Executive Officer, Division Manager of Ikuyaku. Integrated Value Development Division
Yasutoshi Kawakami	Executive Officer Division Manager of Sales & Marketing Division

Presentation

Tabaru: Good evening. I am Eizo Tabaru, Member of the Board, Managing Executive Officer of Mitsubishi Tanabe Pharma. Thank you for joining us at the fiscal 2018 third quarter earnings briefing, despite your busy schedule. I will go over the fiscal 2018 third quarter business results, development pipeline, and progress of Medium-Term Management Plan 16-20. First, the third quarter business results.



Q3 FY2018 Business Results

Open Up the Future

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Q3 FY2018 Financial Results

- **Although Radicava contributed, sales revenue declined because of the impact of NHI drug price revision on domestic ethical drugs, etc.**
- **While working on reducing SG & A expenses, core operating profit declined due to an increase in R&D expenses.**

	FY2018 Q3	FY2017 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	332.4	339.3	(6.8)	(2.0)	435.0	76.4
(Domestic)	236.4	255.3	(18.9)	(7.4)	304.7	77.6
(Overseas)	96.0	83.9	12.1	14.4	130.2	73.8
Overseas sales ratio	28.9%	24.7%			29.9%	
Cost of sales	139.2	134.2	4.9	3.7	176.0	79.1
Sales cost ratio	41.9%	39.6%			40.5%	
Gross profit	193.2	205.0	(11.8)	(5.8)	259.0	74.6
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4
Operating profit	56.4	68.4	(12.0)	(17.6)	67.0	84.2
Net profit attributable to owners of the Company	41.4	52.1	(10.6)	(20.4)	47.0	88.2
Average exchange rate US$	¥111.33	¥111.77			¥105.00	

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

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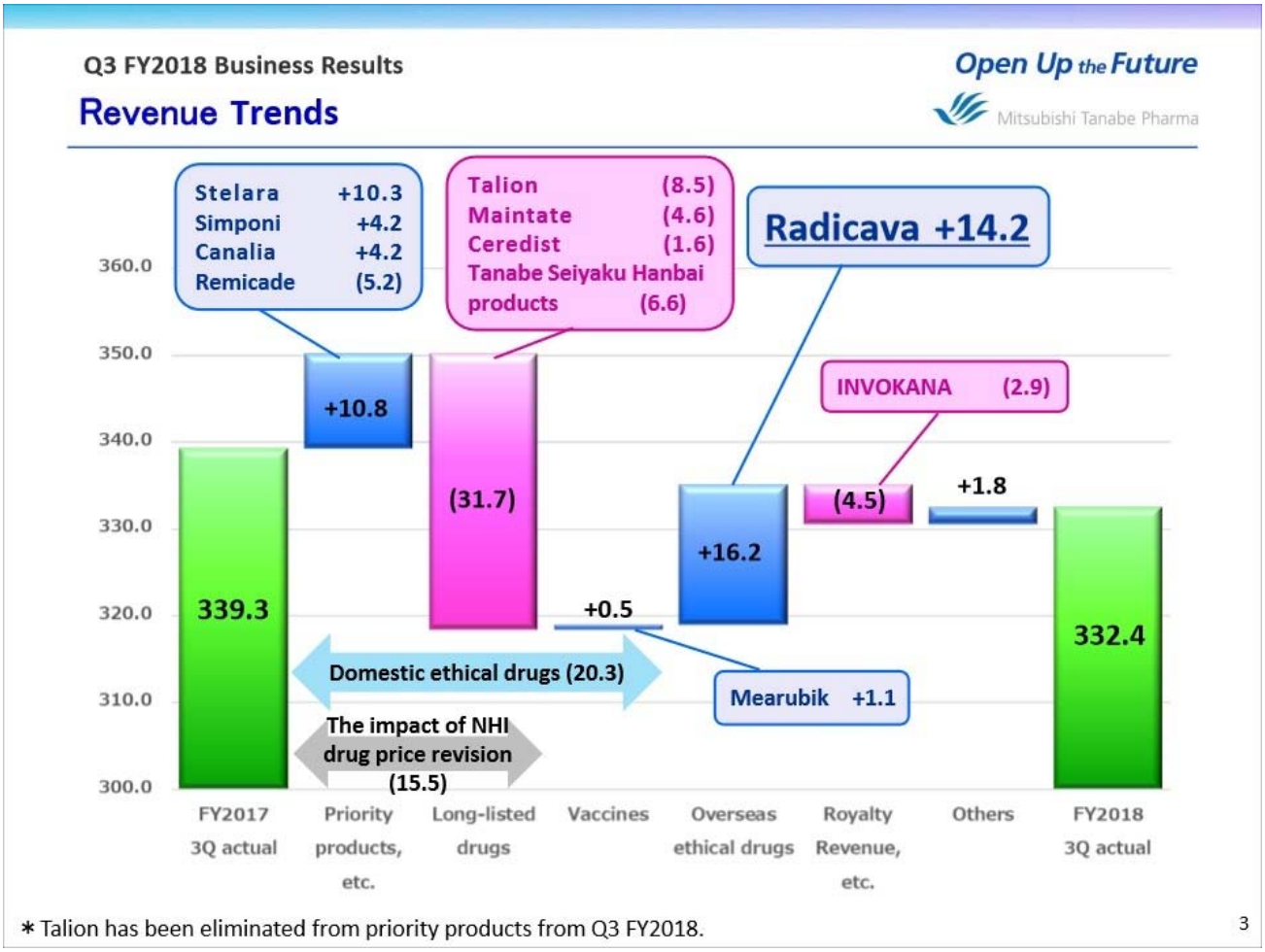
Please turn to page two. Sales revenues felt the continued contribution of Radicava, launched in the US in 2017. Meanwhile, domestic sales of ethical drugs decreased due to such factors as the revision of the NHI drug price, and sales revenue overall decreased by 2% or 6.8 billion yen, year-on-year, to 332.4 billion yen. Gross profit declined by 5.8% or 11.8 billion yen, year-on-year, to 193.2 billion yen. Core operating profit, despite efforts to reduce SG&A expenses, decreased by 14.1 billion yen to 55.5 billion yen, due to an increase in R&D expenses and others. Net profit attributable to owners of the company declined to 10.6 billion yen to 41.4 billion yen.



Next, Revenue Trends. In domestic ethical drugs, there was steady growth in Simponi, a priority product, Stelara, for which we have assumed distribution functions since July 2018, and Canalia, as well as vaccines. But due to the impact of NHI price revision, totaling 15.5 billion yen and a decrease of 6.6 billion yen due to the transfer of generic drugs business, sales overall dropped 20.3 billion yen, year-on-year. In overseas ethical products, sales of Radicava, which began sales in the US in August 2017, increased by 14.2 billion yen, resulting in an increase in overseas ethical drugs by 16.2 billion yen, year-on-year. Regarding royalty revenue, it was down 4.5 billion yen, year-on-year due to the decrease in INVOKANA and others. As a result, sales revenues were down 6.8 billion yen, year-on-year, at 332.4 billion yen.

Q3 FY2018 Business Results

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

- **The sales of cost ratio raised due to the impact of NHI drug price revision and change of product mix, etc.**
- **Core operating profit declined because R&D expenses increased due to progress in the late stage of development, etc., despite efforts to reduce SG&A expenses.**

	FY2018 Q3	FY2017 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	332.4	339.3	(6.8)	(2.0)	435.0	76.4
Cost of Sales	139.2	134.2	4.9	3.7	176.0	79.1
Sales cost ratio	41.9%	39.6%			40.5%	
Gross profit	193.2	205.0	(11.8)	(5.8)	259.0	74.6
SG&A expense	73.1	77.6	(4.4)	(5.7)	101.0	72.5
R&D expense	61.9	56.1	5.7	10.3	84.5	73.3
Amortization of intangible assets associated with products	2.2	1.7	0.4	28.0	3.0	73.4
Other income and expense*	(0.3)	0.0	(0.4)	-	(0.5)	-
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4

＊ Brackets indicate expense and loss.

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

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Next, Cost of Sales, SG&A Expenses, and Core Operating Profit. Cost of sales increased by 4.9 billion yen due to the influence of NHI price revision and changes in the product mix. The cost of sales ratio rose 2.3 points to 41.9% compared with the same period last year. Selling general and administrative expenses decreased due to the transfer of generic drug business and the termination of Bipha Corporation, as well as promotion of business productivity reform, despite increased expenses of US sales subsidiaries following the launch of Radicava. On the other hand, R&D expenses increased due to the progress of the late stage of development, including MT-2271 and the acquisition of NeuroDerm Ltd. As a result, core operating profit decreased by 4.1 billion yen to 55.5 billion yen.

Q3 FY2018 Business Results

Non-recurring items, Net Profit

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	FY2018 Q3	FY2017 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4
Non-recurring items*	0.8	(1.2)	2.0	-	(3.0)	-
Operating profit	56.4	68.4	(12.0)	(17.6)	67.0	84.2
Financial income	0.9	2.0	(1.0)	(51.1)		
Financial expense	0.8	0.2	0.6	244.6		
Net profit attributable to owners of the Company	41.4	52.1	(10.6)	(20.4)	47.0	88.2

* Brackets indicate expense and loss.

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

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Next, Non-recurring Items and Net Profit. Non-recurring items, as you can see, improved by 2 billion yen, year-on-year. Operating profit was 56.4 billion yen, down 12 billion yen, year-on-year. Financial income and expense were as you can see there. As a result, net profit decreased by 20.4% or 10.6 billion yen to 41.4 billion yen.

Development Pipeline

Progress of Major Development Pipeline

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Progress after the financial results for Q2 FY2018

As of February 4, 2019

Development code Product name (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed	Approved
MCI-186 Radicava (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis : ALS)	Swiss				➡	

license-out products

Development code Product name (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed	Approved
TA-7284*1 Canaglu/INVOKANA (Canagliflozin)	SGLT2 inhibitor (Reduce the composite risk of CV death, MI or stroke in type 2 diabetes with established cardiovascular disease (CANVAS /CANVAS-R))	US				➡	
FTY720*2 Imusera/Gilenya (Fingolimod)	S1P receptor functional antagonist (Pediatric multiple sclerosis)	EU				➡	

* 1 Licensed to Janssen Pharmaceuticals (US) * 2 Licensed to Novartis (Switzerland)

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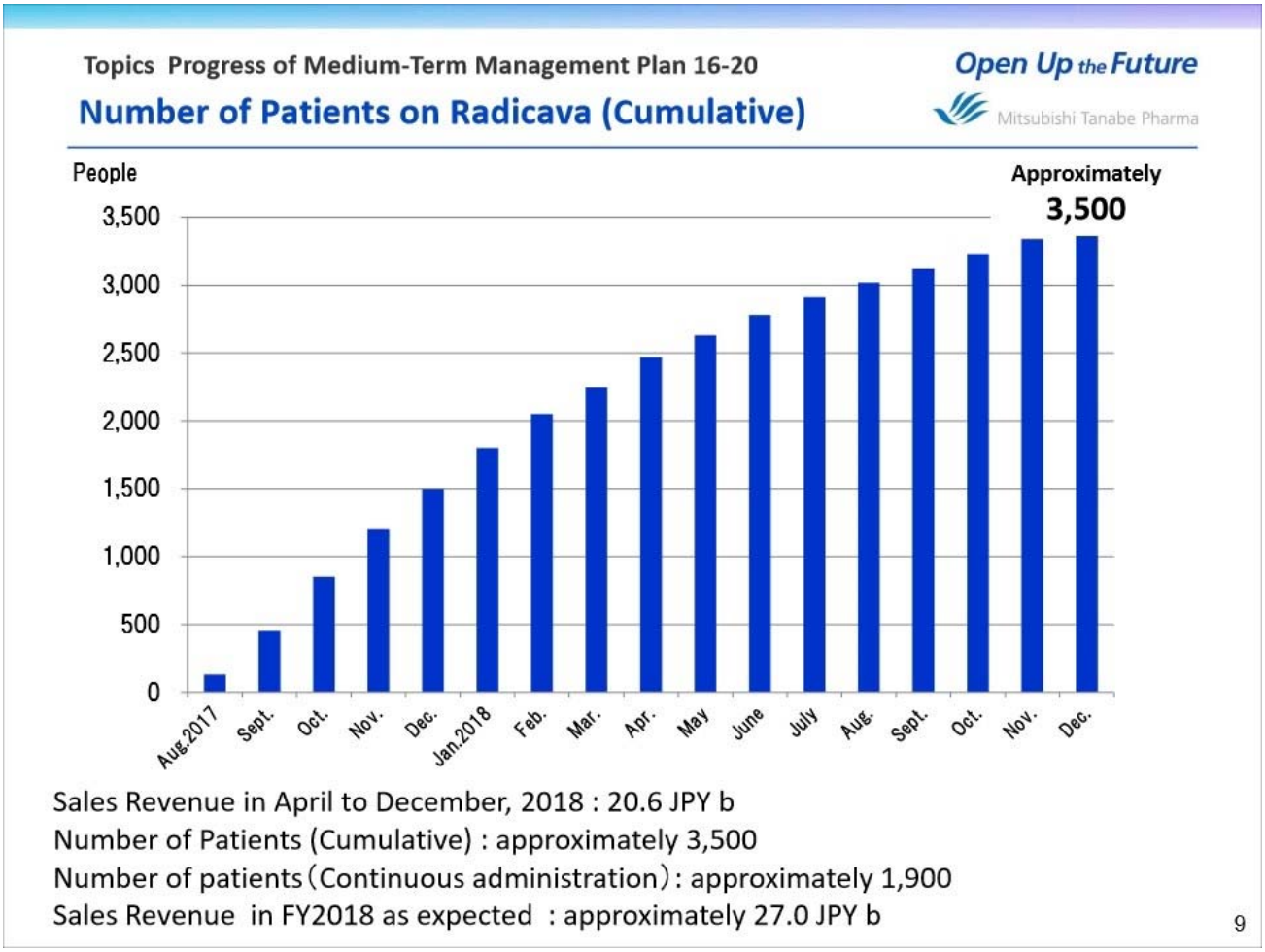
Next, the progress of the development pipeline, page seven. These are the main pipeline projects that have seen progress since the announcement of the second quarter results. First, Radicava, treatment for ALS, was approved in Switzerland on January 31. We will continue to work so that Radicava will reach ALS patients in Switzerland as soon as possible, following the US and Canada.

TA-7284, INVOKANA, which has been out-licensed to Janssen Pharma, received approval in the US in October for risk reduction related to brain and cardiovascular death.

FTY720, Gilenya, out-licensed to Novartis, received approval in Europe in November for pediatric multiple sclerosis.



Next, let me move on to some topics to highlight the progress of the medium-term management plan. Please turn to page nine. Let me first discuss the situation of Radicava in the US. Since we launched Radicava in the US in August 2017, we have been proactively carrying out patient support and promotion activities to help grow Radicava. This chart shows the cumulative number of patients administered with Radicava after each month. Given the trend seen since July 2018, we realized it would be difficult to achieve the initial goal of 31.5 billion yen in annual sales revenue and would wind up at around 27 billion yen. What turned out to be different from the initial assumptions is: A, the number of new patients who have been waiting to and did receive treatment by Radicava is lower than expected; B, ALS is a disease that progresses fast and many of the patients waiting for the treatment to start have become no longer eligible for the criteria to have Radicava prescribed. Considering the number of potential ALS patients in the US is estimated to be 20,000, we are aware that we have not been able to deliver Radicava fully to those patients. And therefore, are determined to step up our efforts to urge patients to start treatment as soon as possible and help them stay on Radicava once they started.

Topics Progress of Medium-Term Management Plan 16-20

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Radicava Business

3P	Achievements	Plans for 2H FY2018
Physician	– Increased field sales activity and physician calls – Physicians have a better understanding of the science of Radicava by education by the field ⇒ Key potential physicians prioritized for greater frequency calls by field representatives.	– Provide information to educate physicians to the Radicava value proposition. ⇒ **Introducing long-term data and scientific development history.** – Development of new scientific data ⇒ Initiate biomarker studies
Patient	– Reduced the lead-time to the start of patient treatment – Enhanced support by nurse educators – Support to facilitate the care environment to help patients living with ALS ⇒ Improve patient convenience and access through additional contracts with infusion centers and home infusion services.	– Improve online access to Radicava information and science ⇒ Utilize digital marketing strategies – Better patient access to Radicava treatment ⇒ **ALS Care Locator** Provide listing of neighboring physicians experienced in the treatment of ALS. (From the end of Jan.) – **Offer out-of-pocket assistance through copay programs and a new copay card.** **(From the beginning of Jan.)**
Payer	– Provide support to initiate and approve the start of treatment – Understand the clinical value of Radicava using science and clinical data – Leveraging post-hoc analyses to demonstrate efficacy	– Educate payers on Radicava's scientific clinical benefit – Work with payers to minimize access restriction to treatment ⇒ **J-code approved to facilitate reimbursement.** **(From the end of Jan.)**

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Please turn to page 10. This is the summary of our new initiatives to the three Ps, who we regard as important stakeholders in selling Radicava. The first P is physicians. We have been so far engaged in activities proactively to provide information and help enhance their understanding, with focus placed on physicians calls by MRs in the field. Furthermore, in the third quarter, we have strengthened our efforts to provide more information on the product value proposition, such as presentations in academic conferences and initiation of biomarker studies.

Next P is patients. Since the launch of Radicava, we have been working to facilitate the care environment to help patients living with ALS. We have been trying to improve patient access to treatment by ensuring more convenient access by patients and their family members to necessary information and by issuing new co-pay cards.

The last P is payers. With regard to insurance reimbursement, currently we are faced with no problems. But in January we had J-code approved to further expedite the reimbursement procedures so that those patients who decided to receive treatment can start as soon as possible. Moving forward, we will continue to encourage understanding and penetration of Radicava, by putting ourselves in those three P stakeholders' shoes.

Topics Progress of Medium-Term Management Plan 16-20

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Progress of Major Development Pipeline

Global Late Stage Products

Development Code	Indications (development stage)	Progress
MT-1186	Amyotrophic lateral sclerosis :ALS（P1)	• Biological equivalence test between oral agent and injection is expected to be conducted in 1Q,FY2019. Long term safety test for ALS patients is planed to be conducted in FY2019.
ND0612	Parkinson's disease (P2)	• Largely agreed with FDA on P3 study design. P3 study is scheduled to be conducted in 2019 summer.
MT-2271	Prophylaxis of seasonal influenza（P3）	• Under consultation with FDA for US filing. Preparing for filing for the elderly and the adult. The initial plan for US filing in FY2018 is expected to be delayed. • Consultation with Canadian authorities for application in Canada is completed. Preparing for application in 1Q,FY2019.

Global Early Stage Products

Development Code	Indications (development stage)	Progress
MT-8554	Vasomotor symptoms (P2)	• P2 study completed. Preparing to conduct P3 study.
MT-7117	Erythropoietic protoporphyria (P2)	• P2 study is ongoing in US. The results are scheduled to be acquired in FY2019.
MT-3995	Non-alcoholic steatohepatitis (P2)	• The results of P2 study in Japan are scheduled to be acquired in FY2019.

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Last but not least, I would like to walk you through the progress of major items in the development pipeline. Among the global late stage products were growth drivers. As for MT-1186, an oral formulation of Radicava, we are planning to perform a biological equivalence study between oral and injection agents in the first quarter of fiscal 2019, and to start a long-term safety study for ALS patients by the end of fiscal 2019.

ND0612 had been undergoing a review on its development plan, but we have largely agreed with FDA on the design of Phase 3 study which is expected to be started around summer 2019.

MT-2271 is still under consultation with FDA for filing in the US and the initial plan to apply for approval in the US by the end of fiscal 2018 is likely to be delayed. We will continue our preparation for filing for approval in adult and elderly patients. Consultations with Canadian authorities for application in Canada have been completed and we are now preparing for the submission in the first quarter of fiscal 2019.

Following these global early-stage products, among which is MT-8554, we have completed Phase 2 study for patients with vasomotor symptoms and are now preparing for Phase 3 study.

As for MT-7117, a Phase 2 study is underway in the US for erythropoietic protoporphyria, and the results are scheduled to be obtained in fiscal 2019.

Furthermore, for MT-3995, we are scheduled to get the results of Phase 2 study in Japan for non-alcoholic steatohepatitis patients by the end of fiscal 2019. That is it from me. Thank you for your attention.

Question & Answer

Analyst 1: I have several questions. I hate to ask the same question every time, but my first question is on ND0612. You said largely reached agreement with FDA on the Phase 3 design. I think you have been looking closely at the possibility of impairment loss. And since you did not mention that this time around, do I take it that we can now assume there will be no impairment loss?

Tabaru: We are still in the process of collecting data on the possibility of impairment loss. Given the schedule was tight in reaching agreement with FDA, we now expect that decision to be made in the fourth quarter.

Analyst 1: So, barring changes to the plan, we will know if there is impairment or not at the time of the full-year earnings briefing. Am I correct?

Tabaru: Yes. That is our expectation.

Analyst 1: I see. Thank you. I have another question for Mr. Tabaru, about the duration of exclusivity of Gilenya. Still undecided, I know. But 2019 guidance of Novartis assumes that there will be no generics launched in the US. In your guidance for the fiscal year ending March 2020, are you also assuming no generics?

Tabaru: We assumed there will be no generic drugs when we revised the medium-term management plan last November.

Analyst 1: I see. Thank you. My third question is on MT-8554. You said Phase 2 study has been completed and now preparing for the Phase 3, which makes me believe that the results of Phase 2 study were positive. To the extent possible, can you comment on when you plan to present a paper at an academic conference? And can you comment on your competitors as well?

Kobayashi: This is Yoshihiro Kobayashi, Division Manager of Ikuyaku. At present, all the data have been collected from the study and we are in the process of tabulating and reviewing them. We will announce the results in due course. As you know, if you wait until all the data from Phase 2 are completely reviewed before starting the preparation for Phase 3, that will be too slow. So, while accumulating data we are making preparations as well.

Analyst 1: I see. My last question, on MT-2271. You indicated that the US filing by the end of March is not likely. The medium-term management plan expects the launch in the 2020/2021 season in the US. Would this schedule be pushed back as well, or can you make it?

Tabaru: Given that after filing there will be sometime before the approval, the launch in the 2020/2021 season will likely be pushed back by one year.

Analyst 1: Were there any issues pointed out by FDA? What's the background?

Kobayashi: This is Kobayashi speaking. In the course of prefiling consultation with FDA, we've noticed a need for further discussion on data interpretation. And that's delaying the process. In the meantime, in Canada, the authority there accepted the current set of data as sufficient for filing.

Moderator: Thank you. Next person?

Analyst 2: I have two questions. First, on your financial results. Compared to the full-year forecast, the profit achievement rates look rather high. Does this mean that there is an upside potential? Or do you expect

expenses incurred in the fourth quarter will bring the full-year results to be in line with the forecast? What is the current status of progress?

Tabaru: So far, we feel that things have progressed steadily.

Analyst 2: Does it mean there is an upside potential?

Tabaru: Upside or downside? Well, it's more on the upside, but not by a large margin.

Analyst 2: The main reason will be expenses to be used as planned?

Tabaru: Yes, given that there is been some lag in the SG&A expenses, and that's having some impact.

Analyst 2: I see. Thank you. My second question is on ND0612. You largely came to an agreement with FDA on the Phase 3 study design. Now in the business briefing in November, you gave us a schedule. Do I take it that things are moving along that schedule?

Kobayashi: Well, the study plan is to first obtain PK data, file an application, and approval. And with FDA, we have largely agreed that comparative study with levodopa and carbidopa oral formulation be conducted, and a study is to start in the summer of 2019.

Analyst 2: In other words, things are moving along the schedule that you indicated in business briefing, correct?

Kobayashi: Yes.

Moderator: Thank you. Next person?

Analyst 3: Thank you for giving us an update on Radicava. My question is on the initiatives on three Ps. You are making such efforts by looking at the current situation. Obviously, the growth has become rather flattish. And for this fiscal year sales revenue expectation has been revised to 2.7 billion yen. So obviously you are lagging behind. But given other factors you believe that you can achieve this, excluding possible impairment loss?

Tabaru: Since there are other factors, both positive and negative, we would like to first look at those closely and take impairment into consideration before deciding on measures.

Analyst 3: I see. For the next fiscal year and beyond you talked about revisiting marketing methods and others. But how effective would they be? Trend-wise, it seemed to be maturing. Do I take it that the current situation is not one that will allow you to regain momentum?

Tabaru: As you can see on slide 10, various measures are being taken and planned. The effect has yet to be felt, not to the extent that we expect. We are focusing on two things: build an environment where treatment can start early, see what support we can provide for that, and the other is to keep the treatment period long. And we are exploring how best to achieve these two. But we have yet to be in a state to say that we've done enough.

Analyst 3: I see. Next question is on impairment loss on 061. I apologize for taking it up again. Based on what you said earlier, am I correct to assume that the study will be carried out in the fourth quarter? Usually the delay means some kind of impairment loss incurred. Are you saying that there will be some impairment but the amount will depend on the trial outcome? Or depending on the outcome, it might become irrelevant? Which is the case?

Tabaru: Well, including whether there will be impairment loss, we are still yet to decide.

Analyst 3: I see. My last question is on MT-2271. Thank you for the information. You were planning a conference presentation but decided against it later, if I remember correctly. Do you have a plan for data announcement at some academic conference now, or given the consultation with FDA, will you refrain from announcing data until that consultation is over?

kobayashi: Since we are talking about Phase 3 results we will be making formal publication eventually. But right now we are in the midst of consultation with FDA. It will be sometime in the future, at an appropriate time.

Moderator: Thank you. Next person?

Analyst 4: My first question is MT-8554 for hot flash. Astellas Pharma is it saying that it will present a paper at an endo conference in March. Do I take it that you will not make it for that conference? And some related questions. What's the dosage regimen? Once daily? Twice daily? And what about partnering? You indicated earlier that Phase 3 is going to be larger in scope and therefore there might be some partnering. Can you comment on that in relation to the start of Phase 3?

Kobayashi: First, making a conference presentation in March is not our target. It will be at a later date that we will be making some kind of announcement. Once POC is established, when we are in the state to present at a conference, we will disclose mechanism dosage regimen and others. So other than it being oral formulation, we cannot disclose any details. In the late-phase development, Phase 3 in particular, the global development, the cost will be larger and therefore, possible partnership. While we are looking for a partner for the sake of seamlessness in the development process, we'd like to prepare for Phase 3 where we can on our own, as well. That's why that description there.

Analyst 4: Just to ask for more clarification, would I be slightly ahead of myself to assume that your partner will be decided before the start of the Phase 3 study?

Kobayashi: We will be making preparations in parallel.

Analyst 4: Does that mean you could start on your own, without a partner?

Kobayashi: That will depend on the situation and on the potential partner.

Analyst 4: I see. Thank you. My next question is about MT-7117 for erythropoietic protoporphyria. If I remember correctly, about three months ago, the Phase 2 study was to be finished in December 2018. But I found in clinicaltrials.gov yesterday that its completion would be September 2019. Did something happen to delay the timetable?

Kobayashi: Initiation of the study, including signing contracts with sites and building a system for clinical operations has been slightly delayed, which has moved down the end of the study by that length of time.

Analyst 4: Am I correct to say that three months ago, you were not aware that the study was going to be delayed? But at the last minute, toward the end of the last year, you realized that it would take more time?

Kobayashi: Yes. You are correct.

Moderator: Thank you. Next person?

Analyst 5: My question is about Remicade. Could you give us updates as to how it is performing, including the impacts from the competition of biosimilars? That is my first question.

Kawakami: Yasutoshi Kawakami, Division Manager of Sales and Marketing speaking. Thank you for your question. As for Remicade, we have been managing to minimize the impacts from biosimilars and expect to see the results for this fiscal year over achieving the plan.

Analyst 5: Could you give me more details on the background? Is it because of the brand equity of Remicade, or is it because biosimilar manufacturers have yet to establish their sales promotion activities? A third biosimilar product has been launched, and the name Pfizer was mentioned as well. How do you think the situation is going to change? Do you have your own outlook to share with us?

Kawakami: As you said, a third biosimilar product has been launched, while a competitor's drug, a new innovative drug for ulcerative colitis has been launched as well. It is true that competition is expected to become more intense going forward. Having said that however, Remicade has been used for many different diseases. Moreover, with RemicheckQ, we expect to be able to recover the performance in rheumatoid arthritis by differentiating ourselves from competition. And we will continue to grow the business to offset the negative factors so that we will be able to achieve the plan.

Analyst 5: Thank you. I have another question on Stelara. I asked a question at the second quarter earnings report. But it seems to be performing quite well. Could you give us the background, including whether you have been successful in taking of more share in the market for this product?

Kawakami: Our understanding is that Stelara business is performing mostly in line with the plan. And going forward, by enhancing awareness on its effectiveness in maintaining remission, low immunogenicity, and its safety profile, we hope to establish its solid position in the market as the first-line biologic product and grow the business further.

Analyst 5: Just for clarification, I understand that you said its cost is high, as it is an in-licensed product. Have you in-licensed with the distribution right only for Crohn's disease and not for psoriasis?

Kawakami: Yes. We are responsible only for Crohn's disease.

Analyst 5: Do you have an option to get licensed for psoriasis as well?

Kawakami: No. We have not considered the option for psoriasis for now.

Moderator: Thank you. Next person?

Analyst 6: I was not able to understand well about Radicava in the US. So, I want to ask a question. In your presentation, you said you had difficulty in identifying patients meeting the criteria. Could you elaborate on what those criteria mean? Moreover, you have been taking countermeasures against the situation and you said you would see their effects in the second half of this fiscal year. But it seems you have yet to see their effects. My question is, whether the issues behind your failure to achieve the plan are solvable with the measures that you have taken so far, if you work on them long enough? And if there is no problem in your current measures, and it is just simply a matter time, then when you expect to see tangible effects?

Kobayashi: With regarding to the criteria, we said many of the patients waiting for the treatment are no longer eligible for the criteria. Some of the patients have rapidly progressing disease and become so severely ill that their physicians made their own judgment. That is what we meant when we said patients are no longer eligible.

Tabaru: Your next question, on whether our current measures will work under the current situation, where there are 20,000 patients with another 400 to 500 newly diagnosed with the disease every month. Our view was that there was potential for more patients to use to use Radicava. And currently we are slightly short of what we thought was achievable. Our current strategy is that if we make improvements on the difficulties that patients and physicians have, including those in administrative procedures, we will be able to hopefully

reach our slightly stretched goals. How long will it take? We will not be able to find out until we actually have done it and receive reactions to sound out. Honestly speaking, we have not yet unable to figure out by when we should see the effects.

Analyst 6: I see. Can the issue of patients becoming more severe cases be resolved with your current measures?

Kobayashi: ALS pathology covers a broad spectrum from those diagnosed quite early, all the way to bedridden patients. Due to the characteristic of the drug, it is difficult to use it for patients at a very advanced or terminal stage.

Analyst 6: Since it is difficult to use the drug to those severe cases, you're trying to capture patients who do not fall under those categories. Am I correct?

Kobayashi: Yes. We also explained it we are going to initiate biomarker studies. It is a fact that hardly any biomarkers that are suitable for ALS have been found. By conducting research on such issues, we are working to encourage early diagnosis and more use of our product.

[END]

Document Notes: *This document has been transcribed based on interpretation.*