



Mitsubishi Tanabe Pharma Corporation

Revision to Consolidated Financial Forecasts for Fiscal Year Ending March 31, 2019

April 24, 2019

Event Summary

[Company Name]	Mitsubishi Tanabe Pharma Corporation
[Event Type]	Analyst Meeting
[Event Name]	Revision to Consolidated Financial Forecasts for Fiscal Year Ending March 31, 2019
[Fiscal Period]	FY2019/3
[Date]	April 24, 2019
[Number of Pages]	11
[Time]	16:30 – 16:51 (Total: 21 minutes, Presentation: 9 minutes, Q&A: 12 minutes)
[Venue]	
[Venue Size]	
[Participants]	approximately 30
[Number of Speakers]	3
Eizo Tabaru	Member of the Board, Managing Executive Officer, CFO
Mikio Himizu	Executive Officer, Vice President, Head of NeuroDerm Office
Yoshiaki Takai	Vice President, Head of Corporate Communications Department

Presentation

Tabaru: Thank you very much for participating in this meeting on the revision to our consolidated financial forecast for fiscal year ending on March 31, 2019, despite your very busy schedule. I am Eizo Tabaru, a member of the board, managing executive officer of MTPC. First of all, let me explain the contents of the revision to our financial forecast for fiscal year 2018.

<div> <div>Open Up the Future</div> <div>Revision to Financial Forecasts for FY2018</div> <div>Mitsubishi Tanabe Pharma</div> </div>					
■ Revision to Consolidated Financial Forecasts for Fiscal Year Ending March 31, 2019					
	Previous forecast* (A)	Revised forecast (B)	Difference (B-A)	Percentage change (%)	(Reference) Results of the previous year (FY2017)
Revenue	435.0	424.5	-10.5	-2.4	433.8
(Royalty revenue, etc.)	(69.8)	(63.0)	(-6.8)		
(Radicava)	(31.5)	(27.0)	(-4.5)		
Core operating profit	70.0	55.5	-14.5	-20.7	78.5
(R & D expenses)	(84.5)	(86.5)	(2.0)		
Operating profit	67.0	50.0	-17.0	-25.4	77.2
Profit attributable to owners of the Company	47.0	37.0	-10.0	-21.3	57.9

*The Company announced full year forecasts on May 9, 2018.

■ **Dividends Forecast**
 There is no change to the year-end dividend forecast from 28 JPY per share announced on May 9, 2018. (Annual dividend of 56 JPY per share)

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Please turn to page one. According to the revised forecast, our revenue is expected to reach 425.5 billion yen, down 10.5 billion yen compared to the previous forecast. Main factors for this difference include a decrease in royalty revenue by 6.8 billion yen, and a decrease in RADICAVA revenue by 4.5 billion yen.

We are making R&D investments for future growth actively. R&D expenses are expected to increase by 2 billion yen from the previous forecast. Core operating profit will fall by 14.5 billion yen from the previous forecast to 55.5 billion yen in the revised forecast. Operating profit is revised downward by 17 billion yen to 50 billion yen.

Profit attributable to owners of the Company is expected to decrease by 10 billion yen to 37 billion yen, according to the revised forecast. As for dividends, there is no change to the year-end dividend forecast, from 28 yen per share we announced on May 9th last year. Annual dividend will be 56 yen per share.

Revenue Recognition of Gilenya Royalty

As MTPC announced on February 20, 2019 in our “Mitsubishi Tanabe Pharma Received Notice of Request for Arbitration,” MTPC is currently in the arbitration proceedings with Novartis Pharma AG (hereinafter “Novartis”), and among the GILENYA® Royalty amounts that MTPC is going to receive from Novartis, MTPC has decided not to recognize some of those amounts, which correspond to the clauses in the 1997 License Agreement of which Novartis has protested the validity, as our revenue because such payments do not satisfy one of the requirements under IFRS15, *i.e.*, “Revenue under contract with customers,” which requires a payment to be made because “the parties to the contract acknowledge the contract, and each signing party is committed to fulfilling the obligations.”

Next, I would like to explain Gilenya royalty revenue, which is a main factor for the decrease in royalty revenue. As MTPC announced on February 20th, 2019, in our news release, Mitsubishi Tanabe Pharma received notice of request for arbitration. MTPC is currently in the arbitration proceedings with Novartis Pharma AG.

Among the Gilenya royalty amounts that MTPC is going to receive from Novartis, MTPC has decided not to recognize as a revenue some of those amounts which correspond to the clauses in the 1997 license agreement of which Novartis has protested the validity, because such payments do not satisfy one of the requirements under IFRS15. It is revenue under contract with customers which requires a payment to be made because the parties to the contract acknowledge the contract. And each signing party is committed to fulfilling the obligations. Next page, please.

Future Forecasts of Gilenya Royalty

With regard to the “GILENYA® Royalty” amounts, during the period of the arbitration proceedings, among the “GILENYA® Royalty” amounts that MTPC is going to receive from Novartis, MTPC will continue the accounting practice of not recognizing those amounts which correspond to the clauses in the 1997 License Agreement of which Novartis has protested the validity as sales revenue, as MTPC does in fiscal year 2018.

In addition, at the announcement of financial results for the fiscal year ending in March 2019, which is scheduled on May 10, 2019, MTPC is planning on disclosing the consolidated business forecast for the fiscal year ending in March 2020. Regardless of the disclosed amounts, MTPC maintains it is entitled to receive the full royalty amounts due according to the 1997 License Agreement with Novartis, and MTPC will rigorously pursue its rights in the arbitration.

As for the amounts among the “GILENYA® Royalty” amounts which will not be recognized as sales revenue, those will be recognized as revenue at the end of the arbitration, depending on the outcome of the arbitration.

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Let me explain how to handle the Gilenya royalty amounts in the future. During the period of the arbitration proceedings, among the Gilenya royalty amounts that MTPC is going to receive from Novartis, MTPC will continue the accounting practice of not recognizing as sales revenue those amounts which correspond to the clauses in the 1997 license agreement, of which Novartis has protested the validity, as MTPC has been doing in fiscal year 2018.

In addition, at the announcement of financial results for the fiscal year ending in March 2019, which is scheduled on May 10th, 2019, MTPC is planning to disclose the consolidated business forecast for the fiscal year ending in March 2020.

Regardless of the disclosed amounts, MTPC maintains that it is entitled to receive the full royalty amounts due, according to the 1997 license agreement with Novartis and MTPC will rigorously pursue its rights in the arbitration. As for the portion of the Gilenya royalties which will not be recognized as sales revenue, that will be recognized as revenue at the end of the arbitration, in accordance with the outcome of the arbitration.

Radicava: Sales in the US (Actual/Expected)

Deviation of the expected

Full year : Forecast 31.5 / Expected 27.0 [Billion yen]

Reason : RADICAVA did not reach the expected number of newly administered patients in the U.S.

[Billion yen]

FY2018 Revenue	1H FY2018		2H FY2018	
Forecast	14.1		17.4	
Actual/Expected	13.9		13.1	
Number of Patients	Q1	Q2	Q3	Q4
Cumulative	2,850	3,190	3,500	3,760
Continuous administration (approximately)	2,000	2,000	1,900	1,900

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Please turn to page four. Next, I'd like to explain our expectation for RADICAVA sales in the United States for fiscal year 2018. Our revenue forecast for FY18 was 31.5 billion yen, but we are now expecting 27 billion yen. In the second half, the drop was mostly ascribed to patients waiting since the launch. The number of newly administered patients did not grow as we expected, which was the main factor for the deviation from the forecast.

Going forward, we'd like to continue efforts to unearth new patients, and reduce economic burden on patients, so we can widely disseminate the value of RADICAVA. In addition, as for the sales forecast in fiscal 2019, will be presented when we announced the business results on May 10th.

■ Background

We have been discussing with the U.S. Food and Drug Administration (FDA) regarding the development plan for ND0612, NeuroDerm's development candidate, and we reached a general agreement with the FDA.

■ Revision in Development Plan

- In our original plan, we were considering backing up "test to clarify drug efficacy and usage" (P3 test, approved in fiscal year 2021), in addition to the main scenario where we obtain U.S. approval in fiscal year 2019 by "PK test with existing drugs."
- In our development plan after review, we will conduct the P3 test in the above. We plan to submit our application in fiscal year 2021 simultaneously in the U.S. and Europe and obtain approval in fiscal year 2022 based on the data from long-term safety tests.

(There is no change from the development plan schedule incorporated in the midterm review and publication from last November)

■ Conclusion

MTPC conducted an impairment test for intangibles related to NeuroDerm products and did not observe any impairment.

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Please turn to page five. I would like to outline the impairment test results pertaining to NeuroDerm products. We finally reached a general agreement with the FDA, whom we have been consulting and discussing with regarding the Phase 3 study design for ND0612 since last year. The entire development plan was finalized accordingly.

Our original plan postulated not only the main scenario of conducting a PK test only to file an application in the US in fiscal 2018 and obtain approval in fiscal 2019, but also, a backup plan to conduct a P3 study to file an application in fiscal 2021.

In the revised development plan, however, the backup plan was delayed by one year. Our feasibility study originally reflected certain development risks, which were calculated based on the probability of success in each of the following three scenarios: The original main scenario, the backup plan, and a failed development.

Based on the broadly agreed development plan with the FDA, we concluded another feasibility study based on the latest market research, as well as current updated status. As a result, we found no impairment pertaining to NeuroDerm products.

■ Situation that includes the main premise

We included the latest market research and changes due to acquisition.

<Negative Factors>

- We have taken into account the delay in the application period and the associated increase in development costs.
- Although we expected drug prices to rise steadily, we re-evaluated given the recent situation of competitor products.

<Positive Factors>

- Although we set an exclusion period in consideration of the risk of launching similar products that avoided formulation patents, but we re-evaluated such risk to be unlikely.
- The discount rate (rebate) was revised based on the latest market research.

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Please turn to the next page. Let me expand on the main premise used for the feasibility study. First, among negative factors, the application period was postponed by three years in the main scenario, and one year in the backup plan, which would entail development cost increase. In addition, although we originally assumed a constant drug price increase, based on the practice of drug price hike in the US, we made a reevaluation based on the recent situation surrounding competitor products.

As for the positive factors, we set an exclusion period that factored in risks of similar products being launched by circumventing formulation patents at the time of acquisition. However, this time, we reassessed that the risk is low, because of the technical difficulties associated with our high concentration formulation. Moreover, because this product will seek approval as a drug device combination product, any generic drug manufacturer would need to make a substantial development investment, raising the entrance barrier.

Finally, the discount rate was reviewed based on the latest market research. Considering the market research conducted by a third-party research firm, as well as the post-acquisition status, we concluded that there will be no impairment, which was also audited by an auditing firm. We believe that ND0612 will serve as an innovative drug that can remarkably improve patients' QoL, by addressing unmet medical needs among Parkinson's disease patients. As a drug device combination product, we expect that it will significantly contribute to our business growth as a long tail product whose value is unlikely to decline rapidly.

With that, I'd like to conclude my presentation.

Question & Answer

Analyst1: I have a few questions on Gilenya. From which date Novartis has protested the validity of the clauses in the agreement, according to your understanding? Since the 20th of February, the date of your news release, or since the 7th of February, the date of the filing of a request for arbitration with ICC by Novartis? This is my first question.

Tabaru: Novartis filed a request for arbitration with ICC on February 7th. With regards to your question on, from which date, we were notified on the 15th of February, when we received the letter.

Analyst1: Then, if it's from the middle of February, some of the Gilenya royalties due in one and a half months were mostly the decrease in the royalty revenue by 6.8 billion yen in the revised forecast? Or more than 6 billion yen decrease in the royalty revenue includes the past portion as well? This is my second question.

Tabaru: Most of the decrease in the royalty revenue, by 6.8 billion yen, is related to Gilenya. As to the calculation period, it's also linked to the contents of the agreement. So, we'd like to refrain from answering this question in detail.

Analyst1: All right. You were saying Novartis has protested the validity of some clauses in the agreement. Is it really just some? When you say some, its weight is not so high, like 10% or 20%? Or should we understand that some could mean 50% or higher? Could you please comment on this? I know this is a difficult question.

Tabaru: Yes. It's a difficult question. The arbitration proceedings have already begun. So, it's difficult to comment on this case.

Analyst1: I believe that your company had discussed with Novartis directly at the beginning. But, you're now in the arbitration proceedings because you couldn't resolve the issues. Could you please let us know around when there were direct discussions between your company and Novartis?

Tabaru: We started our discussions at the end of last year.

Analyst1: You have been discussing since the end of December last year?

Tabaru: Yes.

Analyst1: My last question, I know you may not be able to say it clearly, but in approximately how many months arbitration proceedings will come to an end? Could you give us an idea on its possible duration, like a range in months? How long in general? Can you give us a clue about around when arbitration will end?

Tabaru: It's difficult to say anything definitive about the timeline. We'd like to refrain from commenting on this question as well.

Analyst1: Okay. That's all from me. Thank you very much.

Tabaru: Thank you very much.

Analyst2: There is going to be no impairment in the end, according to latest market research, due to various changes. Regarding delay in the development timing and other factors you have just mentioned, there is going to be no impairment, as long as there is no change in these factors. Is my understanding correct?

Tabaru: Yes, as of now, as long as there is no major change, we are not expecting any impairment according to our understanding.

Analyst2: By intuition, it was difficult for me to believe that there is going to be no impairment. But there was no impairment, even after a few years, because of positive factors. But also, as a long tail product, there was no major impact overall. Should I understand this way?

Tabaru: An exclusion period for formulation patents, as was written on the slide, has been a major factor.

Analyst2: Understood. Thank you very much.

Analyst3: I think my first question may be difficult for you to answer. But still, I want to ask you. Substance patents are still valid. In this amount, 6.8 billion yen looks extremely huge. According to my understanding, use patents are probably owned by Novartis. So, I was not sure about payments to your company. 6.8 billion yen for one and a half months. Is my understanding correct?

Tabaru: That's also related to the contents of the agreement, so I'd like to refrain from commenting.

Analyst3: It will be quite a long time until we come to know the details, correct?

Tabaru: As we mentioned on the 10th of May, we will announce the forecast for fiscal year 2019. On that occasion, we will explain based on the same accounting practice.

Analyst3: Are you assuming a substantial drop from a large amount of royalty in the first quarter?

Tabaru: We will explain on May 10th.

Analyst3: Understood. One more question. On NeuroDerm, the risk of launching similar products that avoided formulation patents was considered unlikely. Does that mean competitors development you are aware of was not going well?

Tabaru: No. In fact, we originally assumed that there would be competitor products, with no specific names in mind.

Analyst3: What are the grounds for lowering the risk in your recent evaluation?

Takai: Mr. Himizu would like to answer your question.

Himizu: The formulation patent features our technology that dissolves levodopa, which is usually insoluble to a high concentration. We devised ways to enable this technology, which is unlikely to be copied by competitors that easily. We reconfirmed that in our recent assessment. That is one reason. Another reason is, because this will be a combination product, as Mr. Tabaru mentioned, the drug can be effective only after it is combined with a device. Therefore, the situation differs from regular generic products in that sense. Even after the acquisition of NeuroDerm, MTPC has examined many things, including improvement of the device or the pump.

Analyst3: Does that mean that the device is different from the original?

Himizu: We would like to refrain from comment at this stage.

Analyst3: I understand. My last question is regarding the discount rate, which you mentioned was reviewed based on the latest market research. Considering the positive factors, the discount rate is lowered, which

seems to be going against the recent trend in the US market, in my observation. Could you give us a reason why this is a positive factor?

Tabaru: it is based on a research report from experts which refer to data on discount rates for the so-called specialty products, as well as mass products by competitors. And, they suggested a certain rate for us this time. Therefore, the rate was derived by considering discount rates for specialty products.

Analyst3: I understand. Thank you very much.

Takai: This is Takai. Let me expand on one thing. Regarding the numbers for the forecast for the next fiscal year, which will be announced on May 10th, royalty revenues will be presented in bulk, as usual.

Analyst4: I'd like to ask two questions. The incident with Novartis took place mid-February, prior to the six-month extension of the substance patent for pediatrics. I wonder whether it has anything to do with the original patent expiration, before the extension. Is that the case?

Tabaru: Because we are in the process of arbitration proceedings, we'd like to refrain from comment on the matter.

Analyst4: I see. Your original announcement included the wording in the US and EU. However, in the EU, you still have exclusive data protection. Am I right? Does it have anything to do with the arbitration?

Tabaru: It is true that we are still in the data protection period. However, we'd like to refrain from comment on what Novartis contends.

Analyst4: I understand. My second question is pertaining to RADICAVA, towards the end. Deducting the figures for a cumulative number of patients, new patients only increase by 260 in the last portion, suggesting that there are fewer new patients. Meanwhile, the number of patients on continuous administration remained the same as that of the end of the third quarter, at 1,900. Can this be interpreted as it has ceased to fall?

Tabaru: At this stage, we cannot say whether it has really ceased to fall. However, we believe that we mostly delivered to patients waiting for treatment.

Analyst4: Patients waiting for treatment were rather severe cases and dropped out after a short period of administration. Am I right in thinking that way?

Tabaru: The disease progression greatly varies among individuals. So, it depends. As for the number of patients on continuous administration, the administration period is not usually that long. Thus, generally speaking, the number of new patients is reaching a stationary phase, as patients waiting for treatment drop out.

Analyst4: I understand. In your upcoming briefing, on May 10th, can we expect to have figures at least from Canada and other countries where the product will have been approved?

Tabaru: We'd like to explain that during our briefing on the 10th.

Analyst4: Thank you very much.

Analyst5: I thought that Gilenya royalty revenue of 6.8 billion was too high. I believe that you hinted that Europe is also included in the areas where royalty revenues are generated. Is my understanding correct? Maybe it is too difficult for you to answer. I may have raised an awkward question.

Tabaru: We'd like to refrain from comment on this, the details.

Analyst5: I shall wait until you announce the guideline on May 10th. That is all for me.

Tabaru: Thank you very much.

[END]

Document Notes

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