Mitsubishi Tanabe Pharma Corporation

3rd Quarter of FY2019 Business Results Conference Call

February 4, 2020

Event Summary

[Company Name]	Mitsubishi Tanabe Pharma Corporation	
[Event Type]	Earnings Announcement	
[Event Name]	Third Quarter of FY2019 Business Results Conference Call	
[Fiscal Period]	FY2019 Q3	
[Date]	February 4, 2020	
[Number of Pages]	20	
[Time]	17:00 – 17:33 (Total: 33 minutes, Presentation: 15 minutes, Q&A: 18 minutes)	
[Venue]	Telephone Conference 3-2-10 Dosho-machi, Chuo-ku, Osaka-shi, Osaka 541-8505	
[Venue Size]		
[Participants]	Approx. 40	
[Number of Speakers]	4	
	Eizo Tabaru	Member of the Board, Managing Executive Officer, CFO
	Yasutoshi Kawakami	Executive Officer, Head of Sales and Marketing Division
	Motoaki Amano	Vice President, Head of Ikuyaku Strategy & Planning Department, Ikuyaku. Integrated Value Development Division
	Yoshiaki Takai	Vice President, Head of Corporate Communications Department
[Analyst Names]	Kazuaki Hashiguchi	Daiwa Securities Co. Ltd.
	Seiji Wakao	Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.
	Tomotaro Sano	J.P. Morgan Securities Japan Co., Ltd.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.

Presentation

Operator: Good evening, ladies and gentlemen. This conference call is for Mitsubishi Tanabe Pharma Corporation's FY2019 third quarter business results. First, there will be a presentation on the overview of the business results for the third quarter for about 20 minutes, followed by a Q&A session. The entire conference call is scheduled to last for about 45 minutes.

Before starting the conference, a cautionary statement. The presentation contains forward-looking statements that are based on a number of assumptions and beliefs in light of the information currently available to management of the Company and are subject to significant risks and uncertainties that may cause actual results to be materially different from those expressed or implied by such forward-looking statements.

I now give the floor to Mr. Takai from Corporate Communications Department.

Takai: We will now begin Mitsubishi Tanabe Pharma Corporation's FY2019 third quarter earnings briefing. Today's participants are Mr. Eizo Tabaru, Member of the Board, Managing Executive Officer and CFO; Mr. Yasutoshi Kawakami, Executive Officer, Head of Sales and Marketing Division; and Mr. Motoaki Amano, Head of Ikuyaku Strategy & Planning Department, Ikuyaku. Integrated Value Development Division. I am Yoshiaki Takai, Head of Corporate Communications Department.

We will first have a presentation on the business results from Mr. Eizo Tabaru and then take your questions.

Tabaru: Thank you very much for taking time out of your busy schedule to participate in Mitsubishi Tanabe Pharma Corporation's FY2019 third quarter earnings briefing conference call. I am Eizo Tabaru, Member of the Board and Managing Executive Officer.

Today, I will cover the overview of the business results, the status of priority products, and development pipeline, followed by the status of becoming a wholly owned subsidiary of Mitsubishi Chemical Holdings Corporation.

Q3 FY2019 Business Results

Open Up the Future

Mitsubishi Tanabe Pharma

Q3 FY2019 Financial Results

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	297.4	332.4	(35.0)	(10.5)	376.0	79.1
(Domestic)	247.2	236.4	10.8	4.6	308.3	80.2
(Overseas)	50.1	96.0	(45.9)	(47.8)	67.6	74.1
Overseas sales ratio	16.9%	28.9%			18.0%	
Cost of sales	143.0	139.2	3.8	2.8	178.5	80.1
Sales cost ratio	48.1%	41.9%			47.5%	
Gross profit	154.3	193.2	(38.9)	(20.1)	197.5	78.2
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9
Operating profit	24.9	56.4	(31.4)	(55.7)	11.5	217.3
Net profit attributable to owners of the Company	18.2	41.4	(23.2)	(56.1)	5.0	364.5
Average exchange rate US$	¥108.89	¥111.33			¥110.00	

※ Announced on May 10, 2019 in the financial results of FY2018

The full-year forecasts for FY2019 remain unchanged

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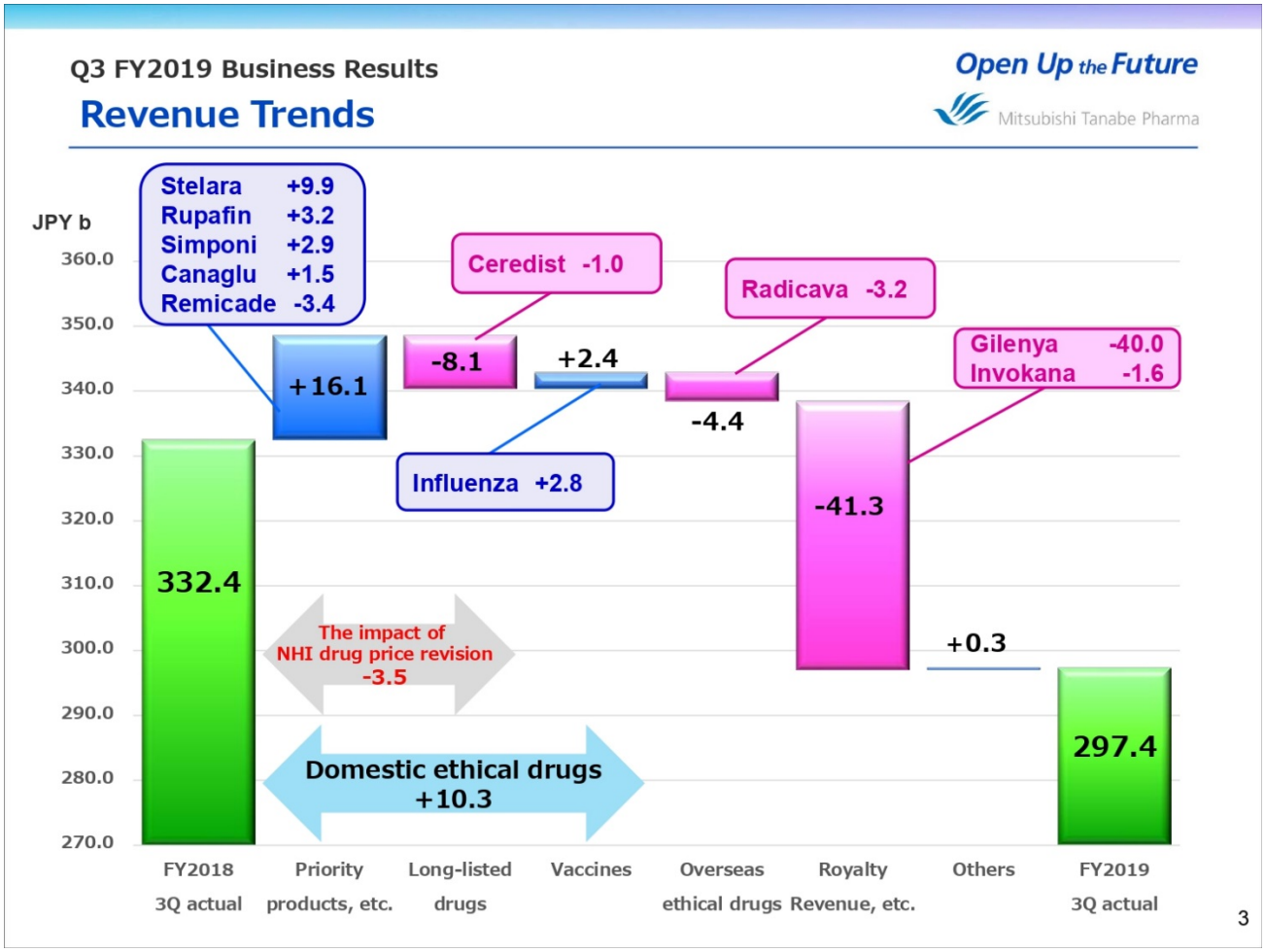
First, business results for the third quarter of FY2019. Please turn to page two.

Among the revenue, sales of priority products in Japan grew during the third quarter, continuing on from the second quarter despite the impact of NHI drug price revisions. On the other hand, Gilenya's royalty income decreased. Due to ongoing arbitration proceedings with Novartis Pharma, a part of the royalty income of Gilenya has not been recognized as sales revenue in accordance with IFRS 15. As a result, revenue declined by 10.5%, or JPY35 billion YoY, at JPY297.4 billion. All of the profit and loss lines were affected by Gilenya royalty and posted a YoY decrease in profit, namely gross profit was down JPY38.9 billion, at JPY154.3 billion. Core operating profit was down JPY31.3 billion, at JPY24.1 billion, and net profit attributable to owners of the Company was down JPY23.2 billion at JPY18.2 billion.

Regarding the full-year forecast, as expenses are incurred almost as planned and are expected to amount to the forecast level, we have made no change to the initial forecast announced in May.



Next, various analysis of revenue.

Sales of domestic ethical drugs increased by JPY10.3 billion, owing to the contribution of Stelara, for which the co-promotion framework with Janssen Pharmaceutical KK was updated last fiscal year, as well as growth in the sales of priority products, such as Rupafin, Simponi, and Canaglu. Overseas ethical drugs declined JPY4.4 billion YoY. Radicava sales were down JPY3.2 billion, mainly because the initial round of prescribing to patients on the waiting list had all but completed, but the sales revenue was more or less in line with the guidance. The total number of patients receiving Radicava totaled approximately 4,500 as of the end of December on a cumulative basis. Royalty income and others were down JPY41.3 billion YoY, mainly due to a decrease in Gilenya royalty and others, as explained earlier. As a result, revenue decreased by JPY35.0 billion, at JPY297.4 billion.

Q3 FY2019 Business Results

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Mitsubishi Tanabe Pharma

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

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	297.4	332.4	(35.0)	(10.5)	376.0	79.1
Cost of Sales	143.0	139.2	3.8	2.8	178.5	80.1
Sales cost ratio	48.1%	41.9%			47.5%	
Gross profit	154.3	193.2	(38.9)	(20.1)	197.5	78.2
SG&A expense	70.5	73.1	(2.6)	(3.6)	99.0	71.3
R&D expense	57.5	61.9	(4.3)	(7.0)	85.5	67.3
Amortization of intangible assets associated with products	1.8	2.2	(0.3)	(15.0)	2.5	74.8
Other income and expense*	(0.1)	(0.4)	0.2	-	(0.5)	-
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9

* Brackets indicate expense and loss.

※ Announced on May 10, 2019 in the financial results of FY2018

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Next, cost of sales, SG&A expenses, and core operating profit.

Cost of sales increased by JPY3.8 billion, and sales/cost ratio rose 6.2% to 48.1%, mainly due to the impact of NHI price revisions, changes in the product mix, and a decrease in royalty income and others.

SG&A expenses were reduced due to the promotion of operational productivity reforms, and among R&D expenses, a part of development project expenses decreased. As a result, core operating profit decreased by JPY31.3 billion, to JPY24.1 billion.

Q3 FY2019 Business Results

Non-recurring items and Net Profit

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	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9
Non-recurring items*	0.7	0.8	(0.0)	(8.6)	1.5	53.1
Operating profit	24.9	56.4	(31.4)	(55.7)	11.5	217.3
Financial income	0.9	0.9	(0.0)	(8.2)		
Financial expense	1.2	0.8	0.4	48.2		
Net profit attributable to owners of the Company	18.2	41.4	(23.2)	(56.1)	5.0	364.5

* Brackets indicate expense and loss.

※ Announced on May 10, 2019 in the financial results of FY2018

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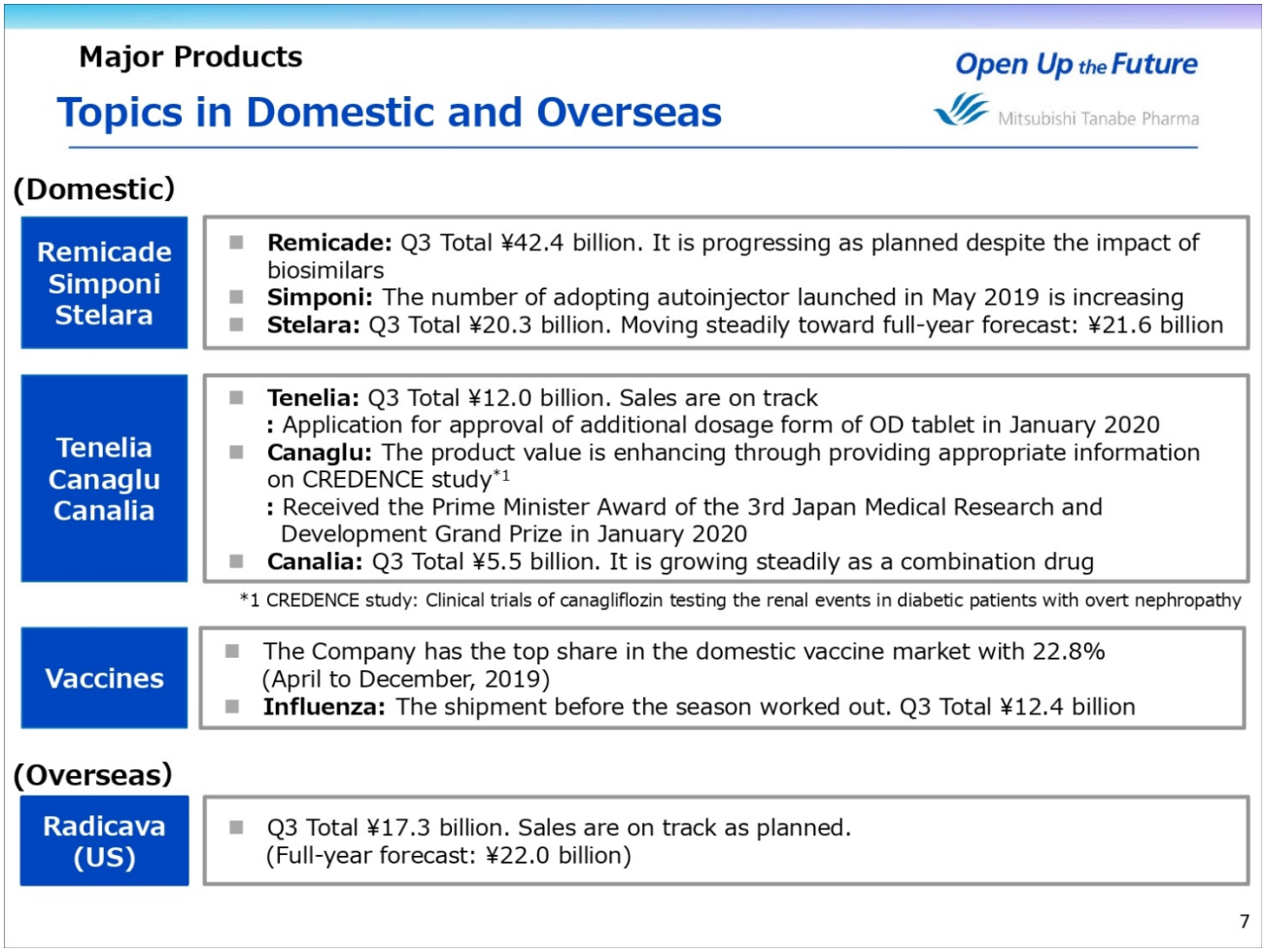
Next, items below core operating income.

Operating income fell JPY31.4 billion to JPY24.9 billion. Financial income and expense were as you can see. Changes in expense reflect the impact of exchange rates. As a result, net profit decreased by JPY23.2 billion, at JPY18.2 billion.



Now, the status of our major products. Please turn to page seven.

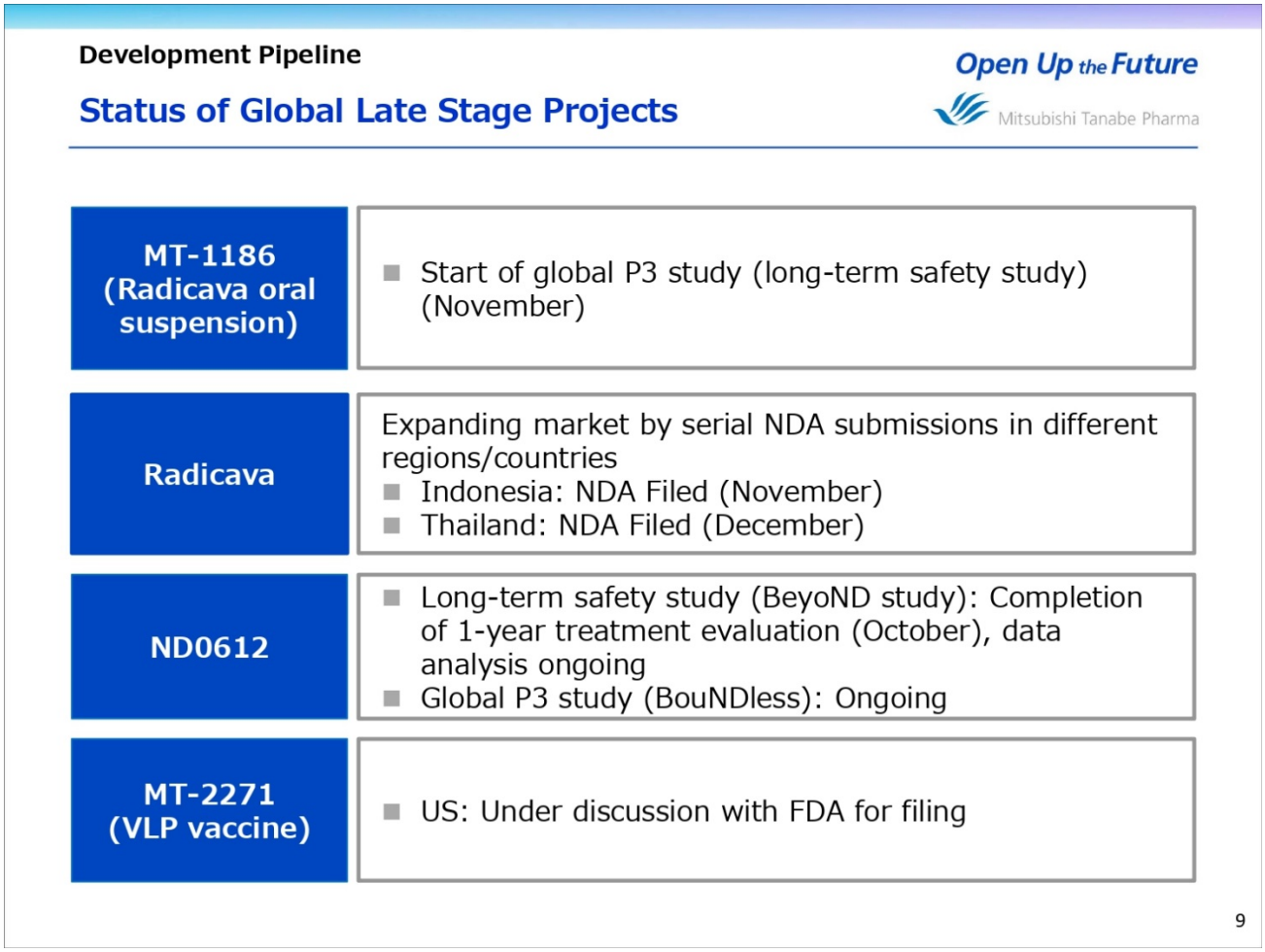
Here are the main topics in Japan and overseas. First, domestic priority products. Remicade, Simponi, and Stelara for immune-mediated inflammatory disorders showed good progress as planned in the third quarter, driving domestic sales revenue.

Next, three diabetes mellitus treatment agents. DPP-4 inhibitor Tenelia, SGLT2 inhibitor Canaglu, and a combination drug Canalia. Tenelia continued to perform well. In January, an application was filed for an additional dosage form for OD tablets that can be taken without water. Regarding Canaglu, we are promoting the contribution of treatment to patients with diabetes by continuing to provide appropriate information on the CREDENCE study announced last April.

Canaglu received the Prime Minister's Award of the Third Japan Medical Research and Development Grand Prize, announced in January of this year. This is the award given in recognition of extremely outstanding achievement.

As for vaccines, we achieved a share of 22.8% in the domestic market between April and December 2019, putting us in the top position in the market. In this season, concern had been raised in the media reports for early outbreak of influenza, but the shipment before the season and other measures taken allowed for a stable supply in the market.

Last but not least, as a major product overseas, Radicava in the US reached total sales of JPY17.3 billion, up to the third quarter, which was in line with the plan. The full-year forecast is JPY22.0 billion.



Let me now discuss the development pipeline. Please take a look at page nine.

I will share with you the status of progress in each of the global late-stage projects. As for MT-1186, an oral suspension formulation of Radicava, which is an ALS treatment drug, we started a long-term safety study in November. Injection formulation of Radicava has been filed for approval in different countries and regions in parallel, and during the third quarter, an NDA was filed in Indonesia and Thailand. ND0612 completed a one-year safety study and is now going through data analysis, and a Phase III study to compare it to oral drugs is currently underway. MT-2271, a seasonal influenza VLP vaccine, is now under discussion with FDA ahead of the NDA submission in the US.

Development Pipeline

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MT-7117 (MC1R* agonist)

MT-7117, an in-house project has achieved POC and started preparations for late-stage development

MT-7117 Features and concepts		■ An oral agent to prevent photosensitivity in patients with EPP ■ Activation of MC1R promotes melanogenesis in melanocytes and prevents cutaneous symptoms caused by ultraviolet light ■ FDA Fast Track designation granted in June 2018
Erythropoietic protoporphyria (EPP)	**Condition**	■ The main symptom is photosensitivity; redness, swelling, blisters and erosions with pain following sun exposure
	Patient Population	■ [Japan, US, and EU in total] approx. 10,000
	Current Treatment	■ Protection from light, administration of β-carotene etc. ■ Afamelanotide, a subcutaneous implant, is marketed in EU and approved in US

*: Melanocortin 1 Receptor

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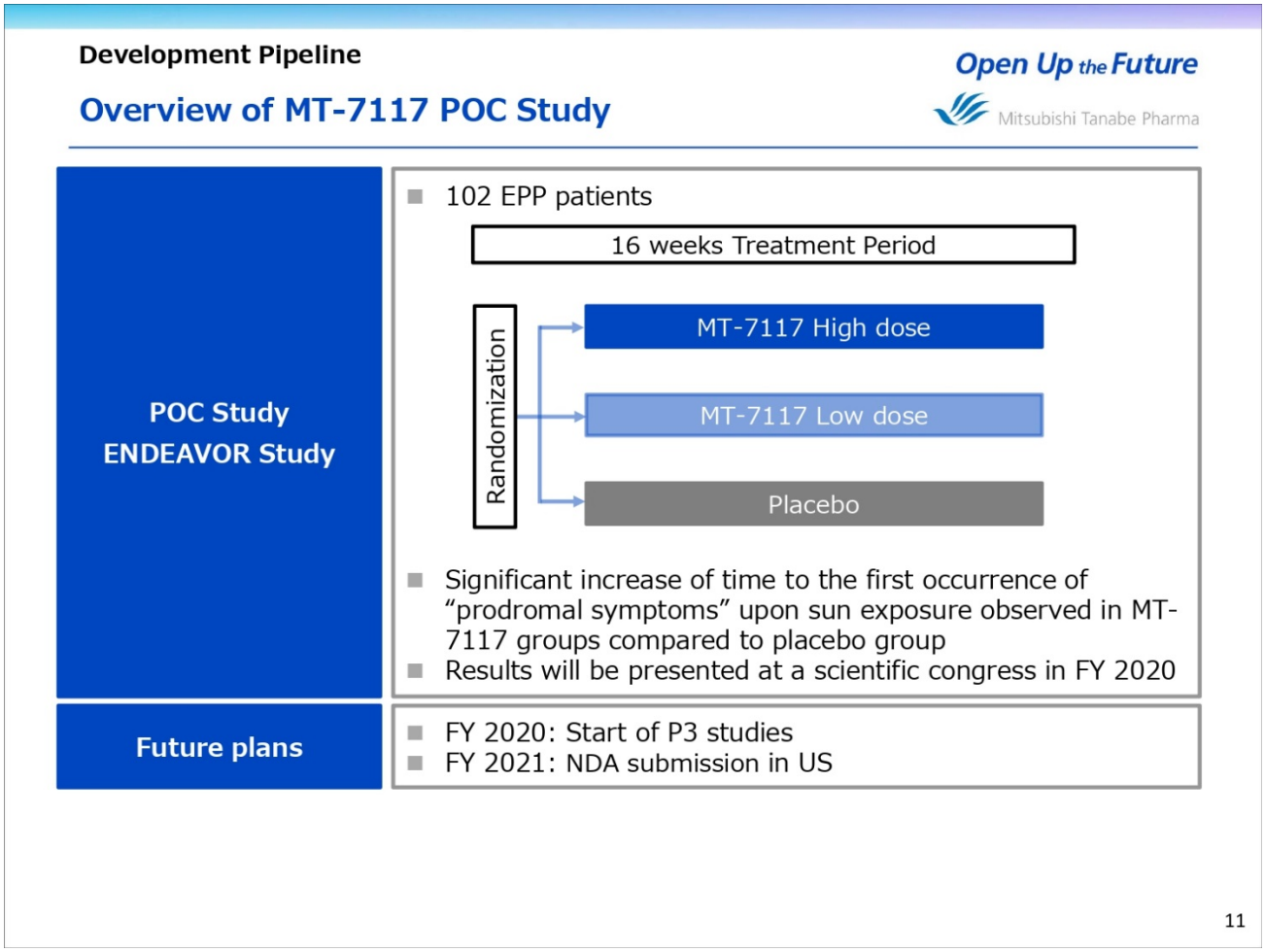
Next, I will discuss each of the projects that have finished POC.

First on MT-7117. We have achieved POC for patients with EPP, erythropoietic protoporphyria, which allowed us to start preparations for its late-stage development. It is now being developed as an oral agent to prevent photosensitivity in patients with EPP and was granted fast-track designation by the FDA in 2018.



This shows an overview of the MT-7117 POC study.

The POC study was conducted for 102 EPP patients, in which significant increase of time to the first occurrence of prodromal symptoms upon sun exposure was observed in the study drug groups, compared to the placebo group. The result of the study is scheduled to be published in the scientific congress in FY2020. The start of the Phase III study is expected in FY2020, and NDA submission in the US in FY2021.

Development Pipeline

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MT-8554 (TRPM8 *1 blocker)

POC study in patients with vasomotor symptoms (VMS) has been completed

MT-8554 Features and concepts		■ Non-hormonal therapy with high safety profile ■ Suppression of VMS by improving Thermoneutral Zone*2
Vasomotor Symptoms (VMS)	**Condition**	■ Hot flashes and sweating associated with changes in hormone levels in the menopausal and perimenopausal periods
	Patient Population	■ Patients with moderate to severe symptoms [US] approx. 10 million, [Japan] approx. 3 million
	Current Treatment	■ 1st line: Hormone replacement therapy (postmenopausal women) ■ 2nd line: Antidepressants (eg, low-dose paroxetine)

*1: Transient Receptor Potential Melastatin 8
*2: Temperature range where a constant body temperature can be maintained by adjusting heat release

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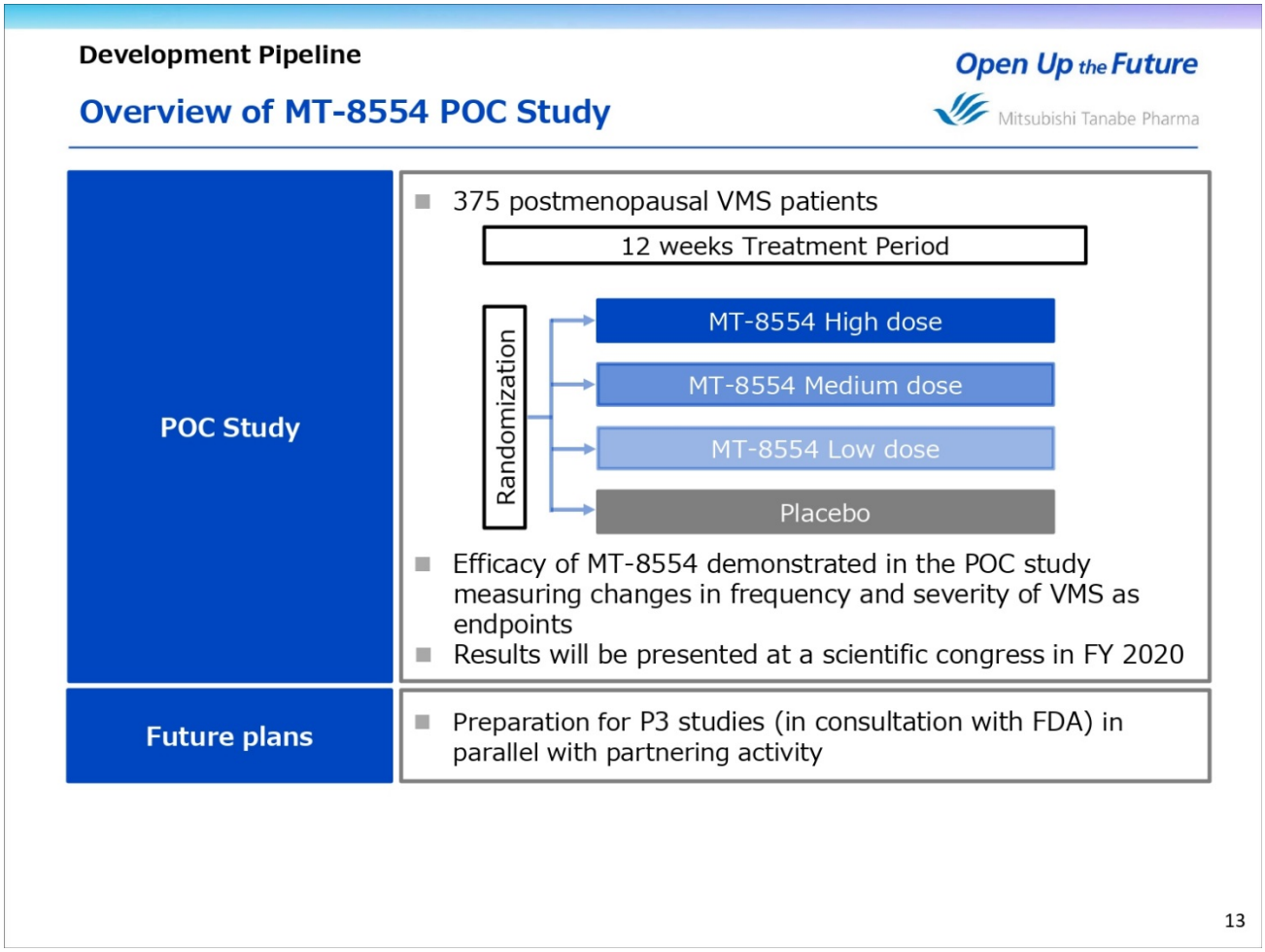
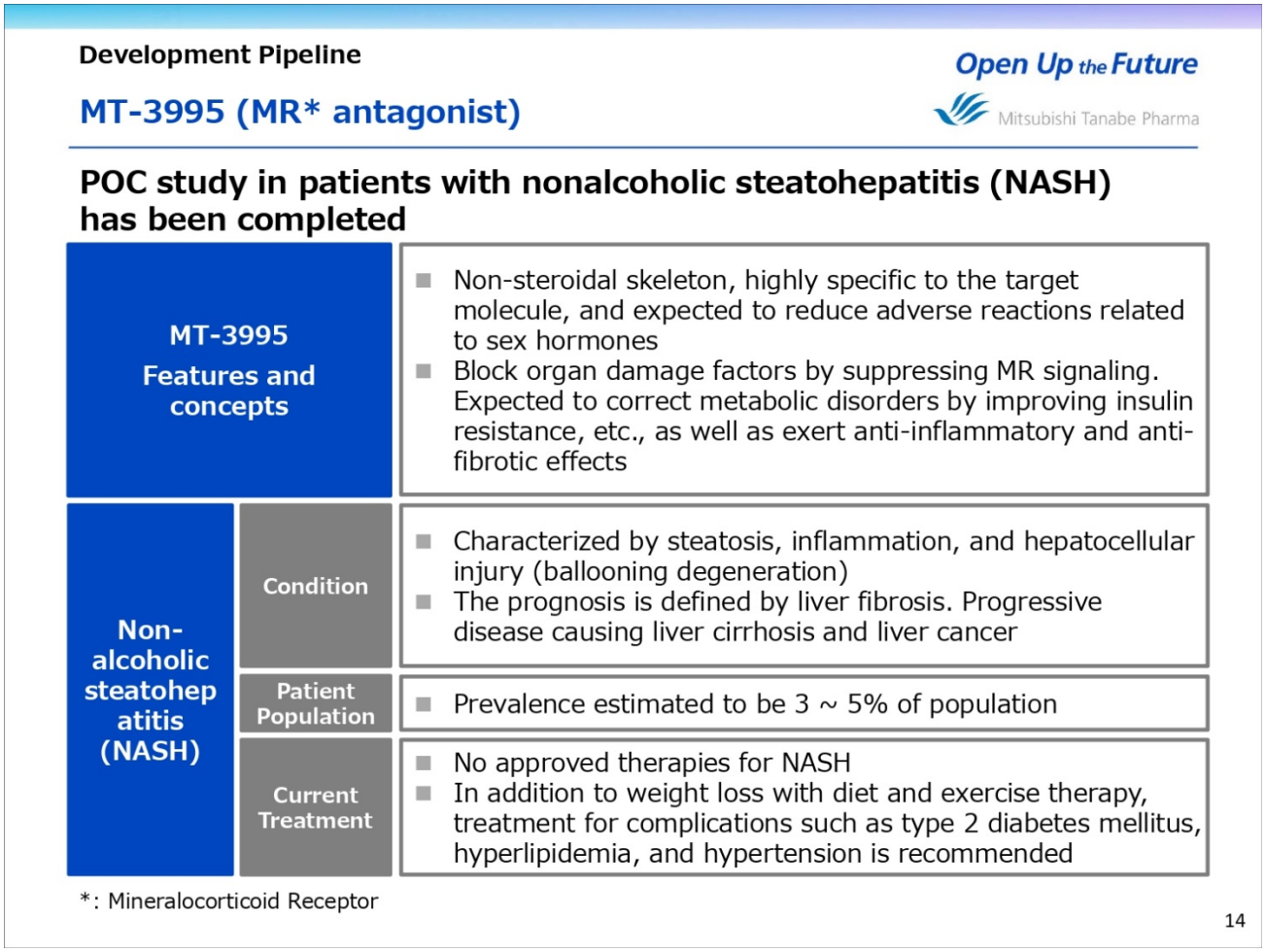
Next, I will explain about MT-8554.

A POC study in patients with vasomotor symptoms, VMS, has been completed. As a non-hormone therapy considered to provide high degree of safety, it is expected to suppress hot flashes and sweating in the menopausal and perimenopausal periods.



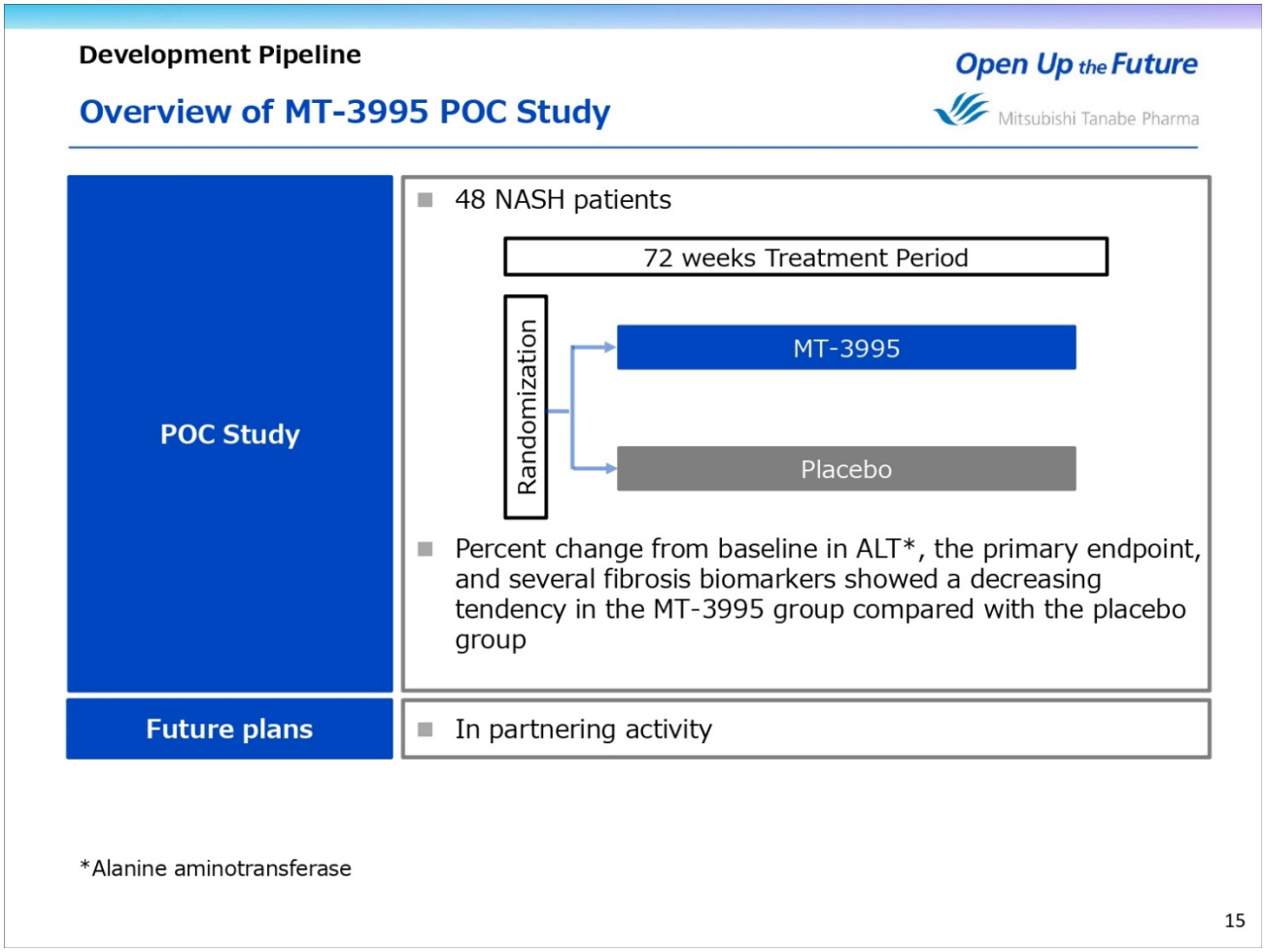
This is an overview of the MT-8554 POC study.

It was carried out for 375 postmenopausal VMS patients, and efficacy of the compound was demonstrated, measuring changes in frequency and severity of VMS as endpoints. Results will be presented at a scientific congress in FY2020. We are now in consultation with the FDA on the design of the Phase III study, while seeking potential alliance partners in parallel.



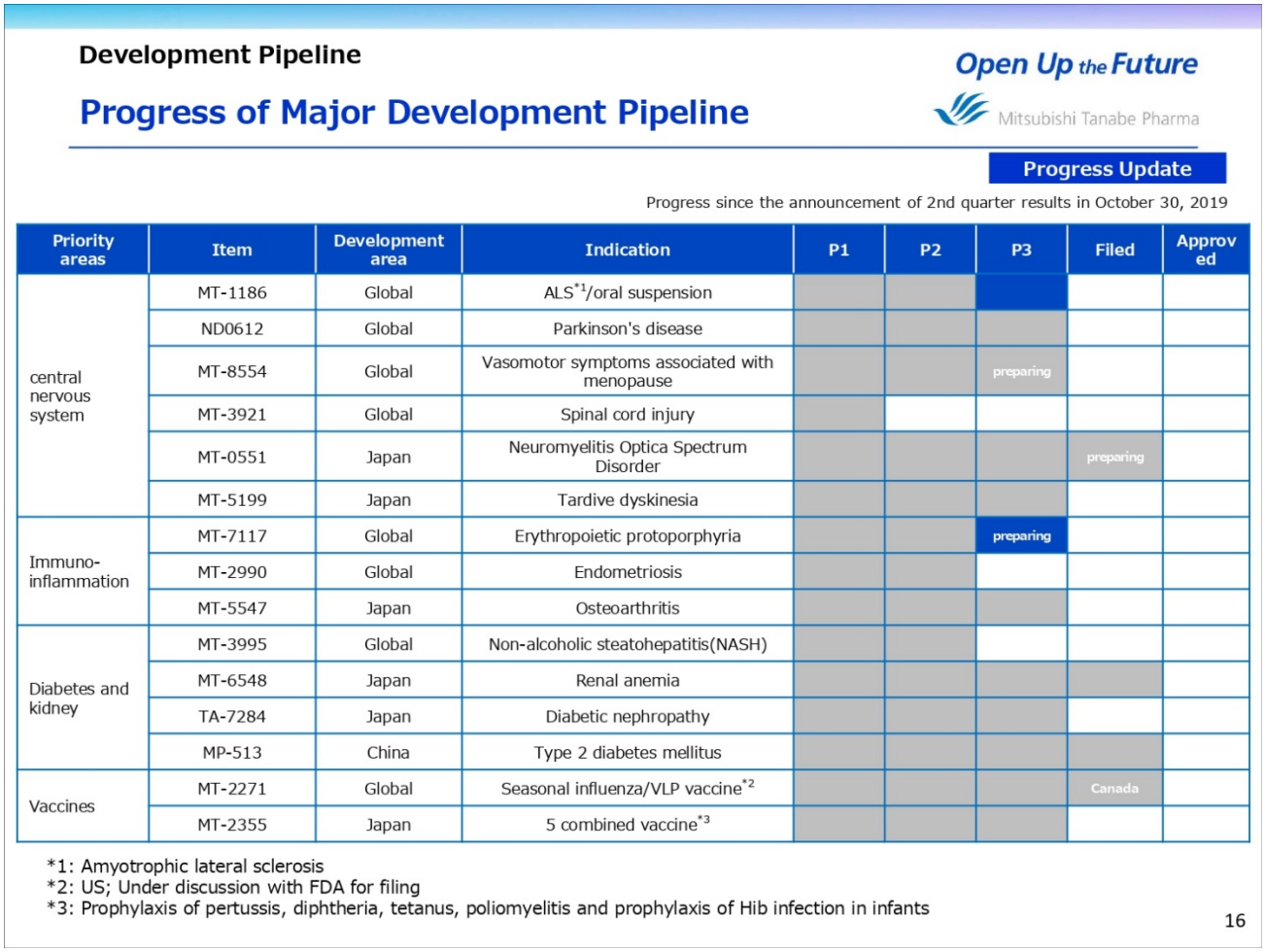
The next project is MT-3995 on page 14.

The POC study in patients with nonalcoholic steatohepatitis, NASH, has been completed. With a non-steroidal skeleton, it is highly specific to the target molecule and expected to reduce adverse reactions related to sex hormones. Furthermore, we can expect it to block organ damage factors by suppressing MR signaling and to correct metabolic disorders by improving insulin resistance as well as to exert anti-inflammatory and anti-fibrotic effects.



This is an overview of the POC study of MT-3995.

The target population was 48 NASH patients. In this study, percent change from baseline in ALT, an indicator for hepatic disorder, and several fibrosis biomarkers showed a decreasing tendency in the MT-3995 group, compared to the placebo group. Partnering activities are underway currently.



Development Pipeline

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Progress of Major Development Pipeline

Progress Update

Progress since the announcement of 2nd quarter results in October 30, 2019

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
central nervous system	MT-1186	Global	ALS*1/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-8554	Global	Vasomotor symptoms associated with menopause			preparing		
	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan	Neuromyelitis Optica Spectrum Disorder				preparing	
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria			preparing		
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
	MT-6548	Japan	Renal anemia					
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2271	Global	Seasonal influenza/VLP vaccine*2				Canada	
	MT-2355	Japan	5 combined vaccine*3					

*1: Amyotrophic lateral sclerosis
*2: US; Under discussion with FDA for filing
*3: Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

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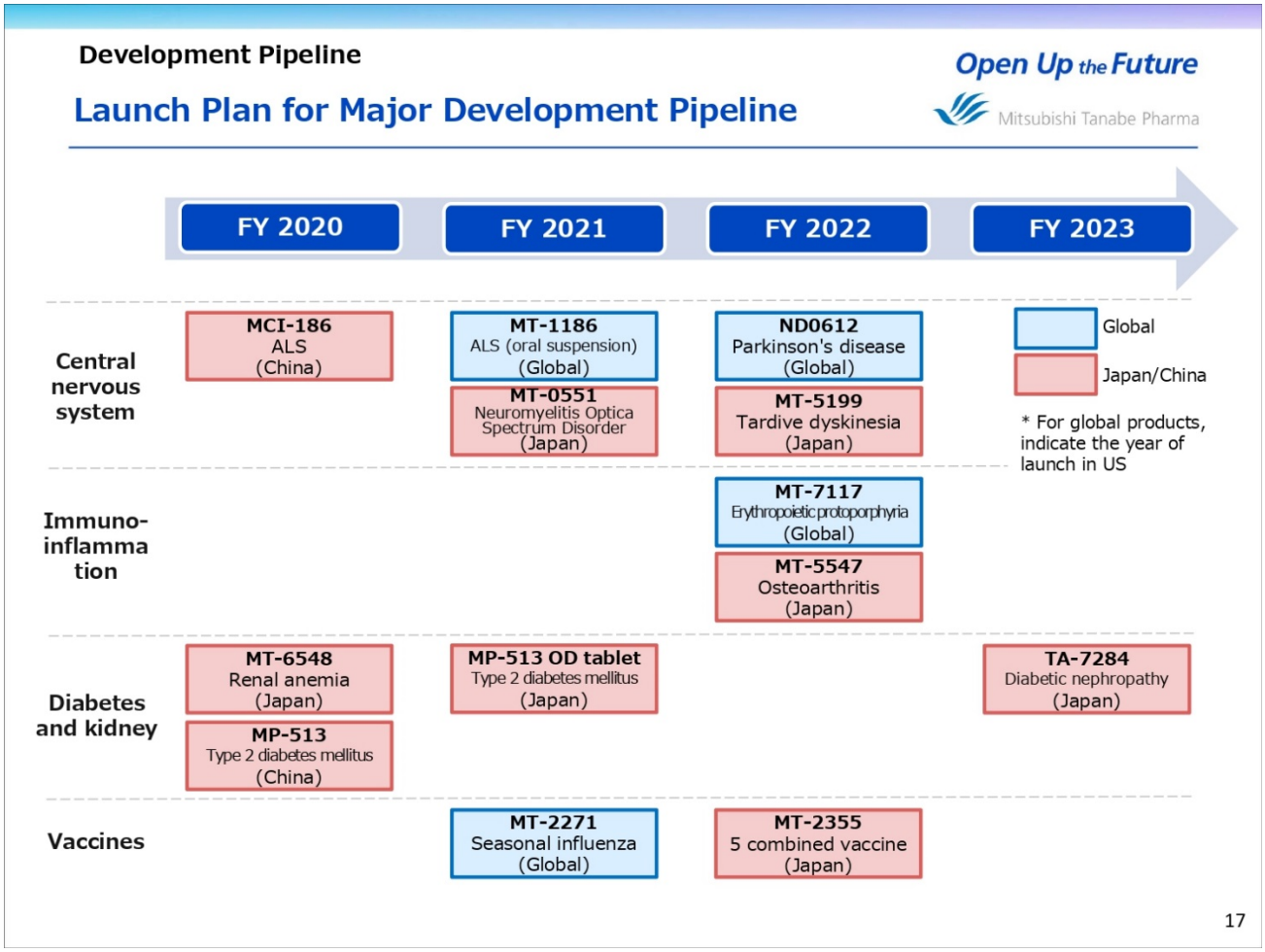
Please take a look at page 16.

Here, you can see the status of the major development pipeline. Those with progress seen since the announcement of the second quarter earnings results are highlighted in blue.



The next page shows the launch plan for the major development pipeline.

Next, let me discuss the status of the plan by Mitsubishi Chemical Holdings Corporation, MCHC, to make us its wholly owned subsidiary.

MCHC, our parent company, on November 18 of last year, announced a tender offer for our common shares and carry it out from November 19, 2019, to January 7, 2020. On January 8, 2020, MCHC announced the results, showing its voting rights ownership ratio reached 91.57%, and on January 17, we approved the demand for the sale of common shares.

Currently, as a next step to become a wholly owned subsidiary, we enter the procedure to sell our common shares. On Tokyo Stock Exchange, February 26 will be our last trading day, and on February 27, our stock will be delisted. On March 2, we are scheduled to become MCHC's wholly owned subsidiary.

That is all from me. Thank you for your attention.

Question & Answer

Operator: We will now take questions. The first question is from Mr. Hashiguchi of Daiwa Securities.

Hashiguchi: Hashiguchi from Daiwa Securities. I have several questions. First is on your R&D expenses. Progress relative to the full-year forecast appears rather low. What are the reasons for that? You said that you expect the actual full-year R&D expenses to be in line with the guidance. What are the reasons for the concentrated spending in the fourth quarter?

Tabaru: Main differences from the original budget include, first, NeuroDerm-related R&D expenses. The Phase III study started in August, which was several months behind the original schedule. And second is in relation to Medicago. Its development expenses are slightly lower than the original schedule. And in Japan, we are adjusting the start of different development projects, changing and shifting the order, which has resulted in some differences from the original budget. The remaining amount is rather substantial, and during the January/March quarter, the 4th quarter, we will be spending quite a bit but, of course, not all. So, we do expect some unspent portion to remain.

Hashiguchi: I see. Thank you. My next question is on Radicava. Can you describe the changes in the number of new patients in the US, a monthly breakdown? Earlier, you gave us the total number, so I couldn't tell if the trend bottoms out or not. Can you give us the figure on a monthly basis?

Tabaru: First, the number of new patients on a monthly basis. Starting with October, there were 120 in October, 80 in November and 70 in December. And in terms of the number of existing patients on continuous administration, there were 1,800 in October, 1,840 in November and 1,810 in December.

Hashiguchi: I see, so I take it that there are no major declining trends. True with some ups and downs on a monthly basis, but it is more or less stable. Am I correct?

Tabaru: Yes, we believe around 1,800 existing patients on continuous basis or continuous administration has now become a baseline.

Hashiguchi: My last question is on MT-7117. The Phase III study is to start in FY2020 for filing in FY2021. Now, the time between Phase III and filing seems short. In terms of fiscal years, it's back to back. Previously, you indicated that there is a possibility of filing based on the POC study results. Are you going to wait until the results of Phase III to become available before you file, or are you considering the possibility of filing before the results of Phase III become available based on POC data?

Amano: This is Amano speaking. Current plan aiming for filing in FY2021 and approval for FY2022 is based on the assumption of conducting further studies. But details have yet to be worked out, as we are consulting with the FDA.

Hashiguchi: So, there is a possibility of filing, not waiting for the results from Phase III. Am I correct?

Amano: If I could repeat myself, filing in FY2021 would be based on Phase III results, but details have yet to be worked out based on the results of the consultation with the FDA. Should it become necessary, we will update the plan.

Hashiguchi: I see. Thank you.

Operator: Next is Mr. Wakao from MUFG.

Wakao: This is Wakao from MUFG Morgan Stanley. My first question is on MT-8554 for hot flashes. You said you plan to present the results to a scientific congress. Can you specify which scientific congress? Based on the POC study results, what kind of advantages do you expect over competing agents?

Amano: This is Amano speaking. Which scientific congress, we cannot comment on that because we are still preparing for the presentation. As for advantages over competing agents, we have yet to carry out further studies, and so, we'll have to wait for the results to come out. But generally speaking, for hormone preparations, certain criteria need to be met in terms of safety and tolerability. In the new profiling of MT-8554, we hope to show some key characteristics through further studies.

Wakao: I see. So, I take it there have been no concern found in terms of safety?

Amano: Currently, as we prepare for the next round of studies, we do not find any issues, but in a larger-scale studies, we will clarify and confirm.

Wakao: My next question is on Invokana and diabetic nephropathy, about the situation in the US, that is. Am I correct to assume that the approval for the treatment of diabetic nephropathy has improved the situation for Invokana? I believe you will be filing for approval for diabetic nephropathy treatment and others in Japan, so I would like to know the impact of this indication. Any information from J&J that you can share with us?

Amano: With regard to sales, I would like to refer the question to Johnson & Johnson, but this is the first SGLT2 inhibitor agent to acquire an indication for diabetic nephropathy in Type 2 diabetes patients. So, we are hoping that we can benefit from that.

Wakao: Thank you. Another question is about you becoming a wholly owned subsidiary of MCHC. I'm interested to know what, if any, specific changes can be expected in terms of collaborations. For instance, MCHC is now working on Muse cells, and is there any plan for you to be responsible for a study following the ones that they have done or for Muse cells business overseas?

Tabaru: This is Tabaru speaking. One of the major challenges in realizing synergy is Muse cells and understanding. Mitsubishi Chemical Holdings, Mitsubishi Chemical Corporation, our Company, and Life Science Institute, LSII, have launched a committee to start discussing this issue more specifically. But we have yet to reach the stage where any decisions or agreements have been made on Muse cells. Everything will depend on the discussions that we are going to have going forward.

Wakao: I see. In terms of timeline, I understand that the data is scheduled to become available in Japan this year. Am I correct to assume that once the data is out, more specific directions can be decided?

Tabaru: MCHC's position is to move Muse cell project forward, and therefore, discussions will take place from the perspective of to what extent are functions going to assist in that regard.

Wakao: I see. Thank you.

Operator: Thank you very much. The next question is from Mr. Sano from JP Morgan Securities.

Sano: Thank you very much. I would also like to ask about the collaborations with MCHC. There was a question on Muse cells earlier, but what about the rest of MCHC's businesses, such as peripheral materials for regenerative medicine or other regenerative medicine businesses or medical gas, for which I guess Taiyo Nippon Sanso will be a partner. Could you give us the update on the progress in your collaborations in those areas, such as establishing a joint committee as well as some future prospects, including what you think could happen?

Tabaru: This is Tabaru speaking. Previously, we explained that a committee to discuss the creation of synergies would be established. In fact, it was already launched at the end of last year and has met two or three times already. For specific items, the four companies are in the process of identifying them by determining what we can do in reality and launching something like a subcommittee composed of those responsible for each of the items. My feeling is that it would take a bit longer for us to be in the position to share more specifics with you.

Sano: I see. Thank you.

Operator: Thank you very much. The next question is from Mr. Muraoka from Morgan Stanley.

Muraoka: Hello, Muraoka from Morgan Stanley. I have a question on the MT-8554 POC study. Did you find all three doses equally promising? Or, do you think you should pick only one dose? You may have commented on this previously, but I do not recall exactly, so could you enlighten me again?

Amano: This is Amano speaking. We're planning to publish the results of our clinical studies soon in the scientific congress, so we'd like to refrain from commenting on the results today.

Muraoka: Is it your position that you cannot comment on this, including whether a Phase III study will be conducted with a single dose, as I did not ask about the results of the study?

Amano: Correct. In particular, the design of the Phase III study is now under consultation with the FDA. Therefore, I'm afraid we should refrain from commenting on the design.

Muraoka: I see. Another question is about collaborations with MCHC in Muse cells. If my memory serves me right, there are four indications targeted, of which one is filed for approval in FY2020, and more is scheduled in FY2021. I, myself, find it not so appropriate to ask for your comment on this, but objectively speaking, given a subtle change in PMDA's attitude toward regenerative medicine more recently, it seems a bit aggressive to aim for filing in FY2020 or FY2021. But do you think it can be done if you end up collaborating with them?

Tabaru: Tabaru speaking again. As for the progress in clinical trials, it is Life Science Institute, LSII, that is taking the lead, and therefore, it is impossible for the company to make any specific comments. In terms of synergy, in seeking commercialization in the future, to an extent, whether we can co-work with them is what we started to discuss.

Muraoka: I see. Thank you.

Operator: Thank you very much. There is still some time left, but since there are no more questions, we would like to conclude the question-and-answer session.

[END]