

# IR Day (Business Strategy Conference) The 2026 Medium-term Business Plan The Q&A

June 11, 2024 13:30 – 14:30 Part 1: Food Segment 14:40 – 15:20 Part 2: Sustainability 15:30 – 16:30 Part 3: Pharmaceutical Segment

#### Speakers:

Part 1: Food Segment	
Katsunari Matsuda	COO (Food Segment), Member of the Board and Executive Officer
Bunjiro Yao	Member of the Board and Vice President, Meiji Co., Ltd.
Part 2: Sustainability	
Jun Furuta	CSO, Member of the Board and Senior Executive Officer
Shinji Matsuoka	Executive Officer, head of Sustainability Management Department
Part 3: Pharmaceutical Se	egment
Daikichiro Kobayashi	COO (Pharmaceutical Segment), Member of the Board and
	Executive Officer
Toshiaki Nagasato	President and Representative Director, KM Biologics Co., Ltd.
Tooru Kurosawa	Member of the Board and Senior Managing Executive Officer, Meiji
	Seika Pharma Co., Ltd.

\*This material has been edited to make it easier to understand some of the questions and answers.



# Part1: Food Segment

#### Q-1-1-1

I would like to ask you about your overseas business in Asia. I think you are planning to increase sales in not only China but in Asia as well.

However, in Asia, there are confectionery products, drinking milk and yogurt as equity method affiliates, and infant formula, so what is the current breakdown of sales? And, having achieved JPY65.2 billion, what will the sales composition be like over the medium to long term? We would appreciate it if you could give us details on your strategies to get there.

#### A-1-1-1

**Yao:** I can't go into the details of sales by category in Asia here, but we are now working on a plan for where we will focus on major growth in the nutrition business for the 2026 Medium-term Business Plan.

As Matsuda mentioned in his explanation, infant formula and enteral formula have unique value. Especially our infant formula cubes, which no one else in the world can produce. We are currently lending technique and know-how for these cube products to Danone in Europe. n the 2026 Medium-term Business Plan, we have a plan to not only lend them to others, but also to actively expand globally on our own initiative.

Therefore, we have set up the 2026 Medium-term Business Plan with a strong expectation for sales growth in the nutrition business, especially in infant formula, enteral formula, and sports nutrition.

## Q-1-1-2

I would appreciate a few more hints, but out of the JPY47 billion increase in sales, should we understand that the majority of this area is really the nutrition business? Also, please tell us if there is any reason why you are now in a position to accelerate expansion in Asia, which you have not been able to do before.



## A-1-1-2

**Yao:** Regarding the ability to do things that were not possible before, we naturally expect organic growth as well. Although we do not yet have a concrete plan for this, we have a business growth plan designed to look at M&A and other opportunities.

#### Q-1-1-3

So, would it be correct to say that the JPY47 billion sales increase in Asia in this Medium-term Business Plan includes some M&A?

#### A-1-1-3

**Yao:** We do not assemble everything with organic growth. It is fine to understand that this includes M&A.

#### Q-1-2

I think you have equity in the drinking milk and yogurt business with CP-Meiji Co., Ltd. in Thailand. What is your medium- to long-term view here?

#### A-1-2

**Yao:** The business with CP-Meiji in Thailand is a very high growth business. However, what is not easily shown in the financial statements is that we have a 40% share control. We are a minority, so we only come in as equity under operating profit in the P/L.

Therefore, I do not often explain the details of our business with CP-Meiji in such a forum, but the business itself is doing very well, and in terms of sales scale alone, it is the largest business in our global business, if we disregard our equity interest. Although we are still in the minority, our technology has been introduced to the plant, and we are taking the lead in the operation of the plant. The CP Group has very strong sales channels especially in Asia.

We are currently collaborating with CP only in manufacturing, but as we expand our business globally in Asia, we will naturally be looking to expand our collaboration with the CP Group,



such as by outsourcing the sales of Meiji brand products in Japan. We are now in the process of discussing with the CP Group.

For the CP-Meiji business in Thailand, there is a bottleneck in raw milk, including exports. Therefore, I feel that the scope of our efforts has expanded considerably when we consider collaborations that include Chinese bases, including the use of our Guangzhou factory.

#### Q-2-1

I would like to ask about the value-adding of sustainable cocoa in the Chocolate business. I remember that you were discussing how to make better use of the parts of cocoa that are thrown away, or how to make drinks using cocoa, or how to commercialize various other sustainable cocoa products.

I would like to know what progress has been made in this area and how it has been incorporated into the 2026 Medium-term Business Plan.

## A-2-1

#### Matsuda:

First, as for the commercialization of sustainable cocoa, the idea is that, especially now, the price of cocoa beans has just skyrocketed, and the quantity itself is not available in the first place. This is largely due to the severe weather fluctuations. I think this phenomenon is also caused by the fact that the economic situation in cocoa-producing countries is not so good, and agricultural chemicals are not being applied properly.

We do not think it is something that will improve anytime soon. Therefore, the sustainable cocoa business concept is to have a stable supply of cocoa beans while creating a sustainable society in which we, the consumer countries, can all enjoy cacao products, such as chocolate. One of the things we are trying to do is to upcycle cocoa, which you just pointed out, to use what is not being used, and we are commercializing this in food and non-food products. As for food products, we also sell cacao nibs before they are turned into chocolate, or the juice that is squeezed from the cocoa itself, on the Internet.



In the non-food products, we are now developing our business by turning cocoa bean husks, which we used to throw away, into fiber for jeans, or cups, etc. We will not only develop this business ourselves, but also we will work together with startup companies and others. Regarding the ceramide business, which we announced in January of this year, we are joining

hands with a cosmetics company. We would like you to understand that we are making firm and steady progress toward becoming a business.

#### Q-2-2

What will be the specific driver of ROIC improvement in the chocolate business in the 2026 Medium-term Business Plan?

#### A-2-2

**Matsuda:** The improvement of ROIC in the chocolate business is based on the profit growth in the numerator. The growth will be generated from the products with our proprietary technology. Such products are considered to bring unique value and expand sales and profits. In addition, regarding the invested capital in the denominator, we will increase efficiency and improve the use of existing facilities that are not being used. We are considering eliminating those facilities that are still unusable and lowering the denominator.

#### Q-3-1-1

I would like to ask about page three of the document, especially regarding the concept of the 2026 Medium-term Business Plan for the dairy business. The initiatives described here to improve ROIC include the establishment of an optimal production system and the elimination of low-margin products.

Once again, I would like to ask you to explain what challenges you are facing in your current dairy business in Japan. Earlier in your explanation, you mentioned that the current Medium-term Business Plan was previously based on the assumption that sales of core business products would grow. Could you please explain once again how functional yogurt is positioned



in the current three-year period?

#### A-3-1-1

**Matsuda:** Regarding the challenges facing the dairy business in Japan, I think the biggest issue is the slowdown in the growth of functional yogurt over the past few years, which had originally been the driving force behind the business. In this regard, we will strengthen our product lineup, as we launched *R-1 The GOLD*, and we will launch products with a strong product concept and performance. This is already planned for this fall.

*R-1* has been able to keep the previous year's level firmly in stores. However, other brands are still recovering. Starting this June, we are working to revitalize the market by launching TV commercials for three sets of *LG21*, *PA-3*, and *Shibou Taisaku Yogurt*. In addition, regarding *PA-3*, the word "purine" can be used in functional foods. This will also be changed as soon as possible to convey the efficacy of the product while using the word "purine" and not just its effect of lowering uric acid levels.

We will do that gradually, starting with those small initiatives, but we expect the recovery of functional yogurt growth.

In addition, *Meiji Bulgaria Yogurt* has been in a difficult situation over the past few years. This is because there were revisions to the raw milk price, so the selling price has gone up twice. Consumer consumption has been slowing down due to price hikes, but since the beginning of this year, we have been able to steadily and significantly clear the previous year's level.

More to the point, we have been able to improve our marginal profit ratio as we have launched compact sizes in addition to 400 grams in line with changes in life cycles among consumers.

In the same way, *Meiji Oishii Gyunyu* is doing very well. Looking at the composition ratio by type and volume, we see an increase in volumes ranging from 900ml to 450ml or even smaller. We believe this is also having an effect on the improvement of product mix.

So, the first step is to recover functional yogurt, and the other products are on the road to recovery gradually. Unfortunately, however, this is not coming back the volume of goods. What I just mentioned is in monetary terms.



Over the past several years, we have invested on the assumption that we would expand sales, but that has not worked out very well. We are thinking of improving ROIC while reducing assets by optimizing the production facilities.

# Q-3-1-2

In what you just said, does the last part about downsizing the production system and asset lightening also apply to the functional yogurt production line?

## A-3-1-2

**Matsuda:** We are working to optimize assets in the domestic dairy business including functional yogurt. That is of course true for FY2024 as well, and we will make firm decisions and take firm actions during this 2026 Medium-term Business Plan.

## Q-3-1-3

Lastly, when you mentioned earlier that the current situation is getting better, were you explaining that the situation is a little better on a monetary basis, including the completion of effects of last year's price hikes, rather than on a volume basis?

# A-3-1-3

**Matsuda:** That's right. For example, *Meiji Bulgaria Yogurt* has exceeded the previous year in terms of a monetary basis, but the volume has not yet returned to the FY2019 before the COVID-19 pandemic.

# Q-3-1-4

I think the effect of the price hike on functional yogurt has run its course in April, but is it still positive on a monetary basis? Regarding functional yogurt, may I just note that you are only talking about *R*-1 that is on sale in stores?



# A-3-1-4

**Matsuda:** For functional yogurt, *R-1* has cleared the previous year in stores. But *LG21* and *PA-3* are still in a very difficult situation

#### Q-4-1

I would like to ask you about the price of cocoa. You mentioned earlier that the price of cocoa has skyrocketed, but I am aware that the assumption of cocoa price has not been factored into the current Medium-term Business Plan and your plan for the current fiscal year.

Do you expect to achieve the profit level in the current fiscal year and the 2026 Medium-term Business Plan with price hikes? How will it be handled? Can you please tell me more about this?

#### A-4-1

**Matsuda:** Regarding cocoa, we will have to consider price hikes after June. Of course, we will need cost control, but we would like to discuss in the future which products we should raise prices and by how much.

Regarding the timing of price hikes, I cannot give a specific date, but we are working to absorb cost increases during the fiscal year.

## Q-4-2

I understand that both chocolate and dairy businesses will be addressed through optimization of production bases, which was discussed a bit earlier.

I understand that today you have in mind to close some production sites, but is this completely forthcoming as a process? Although you cannot say this externally, are you quite ready to do so internally? I would be happy to get some hints or check on the status of this area. If you were to decide and adjust measures internally from now on, it would take years, and it is unclear whether you would be able to implement them within the 2026 Medium-term Business Plan.



#### A-4-2

**Matsuda:** I would ask for your understanding that I cannot disclose the consideration process, but I can answer that we will make a decision and take prompt action during the 2026 Medium-term Business Plan.

#### Q-5-1-1

You have a plan to increase operating profit in the food business by JPY17 billion over the last two years of the 2026 Medium-term Business Plan in FY2025 and FY2026.

Please tell us how much each of the dairy, chocolate and food solutions businesses will contribute to JPY8.5 billion operating profit growth overseas.

#### A-5-1-1

**Matsuda:** Currently, milk and dairy business for consumers in China is suffering, while the rest of the businesses overseas are doing well.

We have already invested in one line of tablet infant formula in Europe and we are working to increase the number of areas where it is available. We also plan to expand our production lines and increase our production capacity for confectionery in the U.S.

Also in Asia, we have already invested in a chocolate production line in Singapore, and it will grow significantly.

In China, in the chocolate category, we have invested billions of yen in a plant in Shanghai.

In terms of sales in China, our *Almond Chocolate* is a best-seller in membership-based wholesale, a growing retailer, and sales are increasing steadily. Therefore, we believe that we will be able to increase sales once the production line is ready.

In addition, food solutions business is going very well, and we expect it will continue to grow. So, FY2024 will be an investment phase, since production will operate from the middle of 2025, so I think it is fair to say that we have a strong plan for the latter half of the 2026 Medium-term Business Plan



## Q-5-1-2

In FY2025 and FY2026, out of the JPY8.5 billion improvement in overseas business, is it safe to imagine that dairy, chocolate, and food solution categories will each contribute about one-thirds each?

# A-5-1-2

**Matsuda:** In line with the revival plan for our dairy business in China, we undergoing a dynamic reform to change its business structure. The loss from the dairy business will be zero, so we hope you will understand that this improvement is also a big positive effect.

## Q-5-1-3

Then the remainder would increase by JPY8.5 billion in Japan. What is the biggest key point here?

## A-5-1-3

**Matsuda:** We believe that this will also grow well in each category, one of which is BtoB. The sales ratio of BtoB to our food segment was just under 7% in FY2021. Compared to other companies, our BtoB sales ratio was low, so there was still room for growth. The reason for the lack of growth was that the dairy products was mainly processed and sold as cream, butter, or nonfat dry milk, but we are now selling products such as a more value-added, highly processed product.

It is also used by a major convenience store as an ingredient in their drink server beside the register. We also provide cocoa beans not only as ingredients for chocolate, but also ganache made from cocoa beans. And the products are sold at a major convenience store too.

In addition, the mix of cocoa and milk is being used by major chocolate cake manufacturers, so we expect growth in the BtoB business. We would like to make our consumer business a stable, solid, and strong foundation, and then develop new growth businesses such as BtoB.



## Q-5-1-4

Of the JPY17 billion increase in profits in FY2025 and FY2026, half is overseas, as you explained today, and the other half is domestic, with food solutions being the biggest driver, is that correct?

#### A-5-1-4

Yao: I hope you to think of it as one of our growth drivers.

I would like to add a few points about overseas business. Regarding the dairy business in China, the revival plan is to bring loss to a breakeven point on an EBITDA basis within the 2026 Medium-term Business Plan. Implementing the revival plan is a key factor in achieving the goal.

Then, we expect the biggest growth in the nutrition business in Asia. We aim to grow by investing management resources, focusing on our unique technology, tablet infant formula. Under the concept of changing the market in the 2026 Medium-term Business Plan, we are now communicating our intention as a group to allocate a considerable amount of management resources to a global market.

While shifting people, goods, and capital to the global market, we are also working to expand our nutrition business, which is one of our greatest strengths, especially in Asia. This will become a major pillar of our overseas sales and profitability.

#### Q-5-1-5

I think in Asia, the nutrition business will grow, but from a profit margin point of view, the planned 5.2% for FY2024 to 5.5% for FY2026 seems like there is hardly any change. Why has the profit margin remained the same even though sales of the nutrition business have increased?

#### A-5-1-5

Yao: I hope you understand that we are taking a conservative approach to profits.



#### Q-5-1-6

Unless we are allowed to discuss on an organic basis, it is difficult to understand from the outside how much and what you are committing to. If possible, it would be appreciated if you could separate the organic portion from the M&A portion, if any, so that it would be easier to see how much commitment you are making. Could you please consider this?

#### A-5-1-6

Matsuda: We will consider it.



# Part2: Sustainability

#### Q-1-1

Regarding the Meiji ROESG, which was introduced in the 2023 Medium-term Business Plan, have you analyzed a correlation between ROESG and stock prices? If there was no difference in correlation, please tell us what issues you think exist and what areas you think need to be reviewed.

If there are examples of other companies that have introduced ROESG, I would appreciate it if you could tell me how your company's position compares to theirs, and whether the stock price valuation is appropriate for that position.

#### A-1-1

**Furuta**: I don't think there is basically much linkage or correlation between ROESG and stock prices. I think that there are some areas where the high ESG ratings are still unfortunately confirmed in terms of the linkage to financial value.

Even so, the introduction of the ROESG has raised awareness of sustainability within the Group, and I believe that this has been a very significant achievement.

Also, I think that people outside the Group understand the concept of ROESG, or the integration and fusion of ROE and ESG. So I am sure that our efforts in this area are also appreciated.

We would like to further promote the concept of ROESG, and we hope that investors will deepen their understanding of ROESG.

## Q-2-1

On page 10, regarding the ROESG target brands in food segment, you mentioned that the current sales composition is 50% in FY2023 and also written the target for FY2024. What is the composition ratio that you would like to achieve in 5 years or 10 years? I would like to know if there is a target number for this.



Perhaps, these fields should be profitable and have a positive impact on P/L. On the other hand, please tell us about your plans for the remaining 50% that are not currently covered. Do you want to upgrade them and put them in the target brand line? Or do you intend to concentrate management resources on the current target line, rather than on the rest, and increase the percentage of the current brand line?

## A-2-1

**Furuta**: First, with regard to the target figures for three years from now, we have not disclosed the net sales figures for three years in this Medium-term Business Plan, so I would like to refrain from disclosing specific figures or percentages for three years from now.

However, as you can see, 50% of food products are our core products and are highly profitable. Therefore, if this 50% becomes 60%, 70%, or if sales growth rate increases, I believe that the impact to our financial performance is also very high.

So, are we going to shrink the remaining 50% down and further down? That's not what we are thinking. We have established these brand lines and products for the time being. If we launch a new product this year, for example, and it becomes a big hit, it will not be included in this line. So, at this point, we are not so much concerned about what to do with the remaining 50% as we are about developing the 50% of the ESG brand that we have set up.

Perhaps a blockbuster product, a new brand, might increase the remaining 50%. We are thinking that way.

## Q-2-2

Will the development of products that meet the Meiji Sustainable Products Certification account for the majority of future product development? In other words, I would like to know whether product development will move in a direction with a greater emphasis on sustainable aspects.

# A-2-2

Furuta: We are currently in the process of applying the Meiji Sustainable Products Certification



## System to existing products.

For example, if a product is very high in sugar or contains saturated fatty acids, the score of the Meiji NPS would not be very good. How to deal with such things is one of the major issues, but I don't think it is a question of losing them altogether and producing only tasteless products such as supplement-like products.

Since it is also necessary to provide tastiness and enjoyment, I think it is necessary to combine those aspects.

That is our thinking for nutritional value, but in terms of sustainability, we will be taking into consideration the environment and human rights in the packaging and raw materials as well. I believe that almost all our products will be sustainable products.

#### Q-3-1

How much would the cost increase if sustainable cocoa is 100% procured? On the other hand, cocoa beans are difficult to procure, so if these unique efforts will help you to secure procurement volume, or if your sustainability efforts will lead to some advantage, please let us know.

## A-3-1

**Matsuoka**: First of all, regarding the cost increase, we purchase cocoa beans at a premium to regular beans. However, the premium amount is undisclosed. The specific reasons for premiums are that child labor is controlled, or deforestation is controlled. We recognize various conditions as premiums and purchase them.

Also, as you know, Ghana is currently experiencing a poor harvest, and as a matter of fact, it is very difficult to procure regular beans. We are also currently unable to purchase the amount we had planned.

However, we were able to procure 70% of the planned amount of Sustainable Cocoa Beans, and we believe that our efforts for sustainability had a positive effect in terms of securing raw materials.



# Part3: Pharmaceutical Segment

#### Q-1-1

On the page for efforts to improve ROIC, there is a JPY15 billion difference in operating profit between FY2024 and FY2026. The main drivers of the JPY15 billion, from what you have explained so far, would be vaccines and antibacterial drugs for infectious diseases, plus *Rezurock* for immunization, I guess.

I think it is a non-disclosure as to which and how much, but I would like to get an idea of how much vaccines and infectious diseases contribute to the total.

#### A-1-1

**Kobayashi:** I think the ratio of profit growth contribution between vaccines and infectious disease drugs is about 6 to 4.

We have not disclosed the profit figures of *Kostaive*. It is something that we can't price on our own so we still need to gather some more information. According to published reports, the price will be about JPY10,000 per unit, and it has been suggested by the Health and Welfare Ministry's Council. Although I am not sure if that will be the case, fall and winter inoculation is implemented with such a price range, as it will be adopted by the regular vaccination Category B, at municipalities.

As to how much we can produce, we are currently looking to produce 4.5 million doses for the fall and winter inoculation. We do not yet know what the time frame will be between receiving application approval and shipping. We will only go forward after receiving the approval.

There is also the vaccination rate issue. Although approximately 20 million people aged 65 or older have been vaccinated in the fall and winter of 2023 vaccination, there is a possibility that the inoculation environment will change drastically, so I would like you to understand that we are taking on various business risks and have budgeted a certain degree.



# Q-1-2-1

And one more thing, on the pipeline page, it may not be a product for a very big market, but the clinical trials of *Hiyasta* for R/R DLBCL has been going on right now. Sorry for my ignorance, but the primary endpoint is ORR (overall response rate).

## A-1-2-1

Kurosawa: Yes, exactly.

## Q-1-2-2

I think that in Japan, the main therapies for R/R DLBCL are BR therapy with Bendamustine and *Rituxan*, or PBR therapy with *Polivy*. What is the position of this drug in contrast to those therapies?

## A-1-2-2

**Kurosawa:** This drug has a high safety, so I think it would be very advantageous to elderly patients. We expect that the efficacy will be about the same, so we think that the drug is easy to use, including in combination with other drugs.

# Q-1-3

I have a question about PDE4 inhibitors. I think there is already a drug on the market with the same mechanism of action, so how would you differentiate it?

## A-1-3

**Kobayashi:** One PDE4 inhibitor, such as *Apremilast* which is famous drug for psoriasis, has sold about JPY300 billion worldwide. As you say, it has exactly the same mechanism of action, but just because it has the same mechanism of action does not mean it has the same effect. We are not able to disclose detailed data yet, but looking at the data up to Phase IIb in the US, the level of efficacy is expected to be much higher than that of the existing drugs.



As you are aware, oral drug treatments for psoriasis are shifting towards novel JAK inhibitors, TYK2 inhibitors. On the other hand, patients in the immune-inflammatory field suffer not only from psoriasis, but also from atopic dermatitis, rheumatism, and other diseases. We believe that patients who are being treated with expensive biopharmaceuticals will continue to need extremely safe drugs such as PDE4 when they complete their biopharmaceutical treatment and are followed up by private practice doctors.

However, I understand that PDE4 has been somewhat lacking in therapeutic efficacy as a treatment, and I believe that we can raise that level to a much higher level.

We are about to enter a Phase III trial, and the FDA asked us what is the value that can only be achieved with this drug, so we have agreed on a comparative trial. If we can achieve this trial, it means that we can represent a therapeutic superiority over the existing PDE4 inhibitors. We will not know the results until we see them, but we believe it is a drug with the potential to achieve. We will be able to publish the data in a little while, so please stay tuned.

## Q-2-1-1

We have heard about various growth drivers, such as vaccines, antibacterial bulk drugs, domestic generic drugs, and overseas. Where do you see your greatest expectations right now?

Also, I understand that the vaccine sales and profit contributions will probably occur over the next three years, and the antibacterial bulk drugs contributions will probably take effect over the next Medium-term Business Plan.

While organizing that time horizon as well, please tell us what areas contribute to the sustainable growth of your company.

# A-2-1-1

**Kobayashi:** What we are most looking forward to in the near future is the launch of *Kostaive* and its distribution.

By collaborating with ARCALIS, we will have a domestic manufacturing platform for this new



next-generation vaccine, from drug discovery to R&D to formulation. We would like to launch this vaccine in 2024, and the economic value should be clarified.

In FY2024, we aim to launch a domestically produced COVID-19 vaccine. On the other hand, since the vial is not as convenient as existing COVID-19 vaccines, we believe that there will be a slight delay of about one lap.

We anticipate that the full-scale entry of our COVID-19 vaccine will be in FY2025. At that time, I am sure that the inactivated vaccine we are working on is ready to be launched, we would like to establish a platform for infection control in Japan using these two modalities. In this context, we are also working with several companies, so we would like to work together to build this platform.

Furthermore, the self-amplifying mRNA modality, was just converted to the COVID-19 vaccine, and the original clinical target is not there. At academic conferences in the US, there has already been a lot of basic research on cancer treatment using self-amplifying mRNA. Since we have a platform, we are looking to take it to the next step soon.

Nagasato: I will talk a little bit about the existing vaccines and others.

KD-414, an inactivated COVID-19 vaccine for children that we just mentioned. As you know, we are developing it by using XBB strain, but we plan to develop it by incorporating the next mutant strain. And our policy of launching the product during the 2026 Medium-term Business Plan has not changed in any way.

And now we have launched the five-in-one combination vaccine, the existing four-in-one combination vaccine plus Hib vaccine. In addition to this, we are developing a six-in-one combination vaccine that adds the hepatitis B vaccine at warp speed, and Phase II will begin soon.

We believe this will be the final form of a combination vaccine. This is supplied by two companies, as there is only one other competitor in Japan. We are now thinking about how to obtain approval as early as possible.

In addition, although I cannot provide details at this point, we would like to swiftly expand our



smallpox vaccine business globally during the 2026 Medium-term Business Plan, of which only two other companies in the world have it.

Another big one is the influenza vaccine, which now has the largest market share in Japan. It is expected that the vaccines will change from a quadrivalent vaccine to a trivalent vaccine after next year. We believe that this will undoubtedly lead to increased domestic competition. Since there is a shortage of influenza vaccines overseas, especially in neighboring Asian countries. We would like to export influenza vaccines to Asia as early as possible in the 2026 Medium-term Business Plan.

## Q-2-1-2

When you announced the 2026 Medium-term Business Plan at the last financial results briefing, you said that you expect to increase sales of human vaccines by about JPY24 billion in the current fiscal year. And you plan to increase sales by about JPY14 billion from FY2024 to FY2026 toward the final year of the Medium-term Business Plan.

I think that the COVID-19 vaccine, including the *Kostaive*, will take effect in earnest in the next fiscal year, so I am wondering if it is correct to say that you are aware that you will be able to achieve these figures with a high degree of certainty, even if there is some delay.

# A-2-1-2

Kobayashi: Yes, exactly.

# Q-2-2-1

I wanted to ask about bulk drugs. If antibacterial bulk drugs are produced domestically, what is the size of the market and what is your company's potential position in it?

# A-2-2-1

**Kobayashi:** Currently, three companies, including us, are working on a project for internal production of beta-lactam. The 165-ton tank shown on page 32 is enough to make all of



Japan's domestic bulk drugs.

We will create this system to produce enough bulk drugs to supply the entire domestic market until 2025. Under normal circumstances, the plan is to produce half of the amount here, while of course importing inexpensive bulk drugs from overseas.

The bulk drugs produced in Japan will naturally be more expensive than those made overseas. So the government is in the process of discussing ways to address the difference in price between the bulk drugs produced in Japan and those from overseas.

Shionogi & Co., Ltd. is producing cephem, and we are in charge of penicillin formulation. As of now, for the bulk drugs made by both companies, we are suggesting that it would be better to have the government buy them, and return them to the market at a fair price, as they are important supplies for national security.

When these two bulk drugs are produced in Japan, it is a policy issue how to fit them in the ecosystem, which has not yet been decided.

# Q-2-2-2

The framework hasn't been decided yet.

## A-2-2-2

**Kobayashi:** That's right. But I don't see this as a negative. I understand that the public insurance system must be properly organized in terms of accountability for what the government should purchase as well as in terms of antitrust law.

First of all, the premise is that the companies participating in this in-house production of bulk drugs are economically rational, so I am not that worried about it.

# Q-3-1

I would like to confirm the outlook for sales and profits in the 2026 Medium-term Business Plan for the pharmaceutical segment.

Looking at the materials for the 2026 Medium-term Business Plan, I believe while you estimate



a 44% increase in overseas business and sales of the 2026 Medium-term Business Plan compared to FY2023, profits were down compared to FY2023.

I think that the direction of growth you mentioned today is quite promising, but when will it be visible in terms of sales and profits? Could you tell me the outlook in categories like domestic, overseas, and vaccines?

#### A-3-1

**Kobayashi:** As you just pointed out, overseas sales are expected to increase in FY2026, but profits are expected to drop significantly. Until now, the pharmaceutical segment as a whole has controlled R&D expenses, sales, and profits. But, in order to manage ROIC by business category like domestic, overseas, and vaccines, we have decided that the R&D investment associated with that business will be attached to that category.

Overseas, profits before R&D expenses are expanding steadily. During the 2026 Medium-term Business Plan, many global products are entering the final phase of Phase III trials. It would cost a very large amount of money, especially in the final year. For this reason, if R&D expenses are allocated to the overseas category for global products to be implemented after the 2026 Medium-term Business Plan, we end up with this kind of distorted plan.

For example, in the 2026 Medium-term Business Plan, the target profit of the pharmaceutical segment is JPY40 billion. Since the R&D investment at that time will be about JPY24 billion, we estimate that the profit before deductions will be JPY64 billion to JPY65 billion.

Initially, many of our products were developed domestically, but from now on, we will shift our R&D investment to overseas products. However, since overseas sales are not that large at the moment, the figure would be distorted if we subtracted them from the total.

## Q-3-2

As you mentioned earlier, you have included the COVID-19 vaccine in your plan for FY2024, but do you mean you rather make a full contribution from the sales for the base of the 20 million vaccinators in FY2025? Is this a way to create a plan that says that profits will increase a bit



more in FY2025 and that you are not looking at full profits in FY2024?

#### A-3-2

**Kobayashi:** That's right. First of all, we were behind schedule in the development of the vaccine, so we completed the development in seven months from the approval application in April 2023 to the approval on November 28. And now we are finally working on the JN.1-compatible mutant strain. The manufacturing also has its validation and various other things, so we are not getting the manufacturing scale as we would like, so we stay at 4.5 million doses in 2024.

Moreover, each vial contains 16 doses, which means they are slightly less convenient.

We still don't know how much production we will have in 2025 when we make the vials more convenient, but I think it will probably be about 10 million doses.

Ultimately, once domestic factories are implemented, this will have the production capacity to produce enough for the entire nation. It will take until 2027.

#### Q-4-1-1

Earlier, in the business strategy for vaccines and other businesses on page 28, I believe there was a category called newborn screening. What do you mean by improving the business value of this category?

#### A-4-1-1

**Nagasato:** This is a little-known business, but it involves screening newborn babies to detect birth defects.

Everyone receives this service at public expense. We have been calling it mass screening, which is like a physical examination of a baby. Now, however, many therapies, including gene therapy to cure various birth defects, are developing at a tremendous pace.

In the old days, the disease would have killed them within a year of birth. For example, congenital immunodeficiency disease, which we call SCID, and also congenital spinal



muscular atrophy, which we call SMA. Babies with these genetic diseases used to die, but now they can be completely cured with gene therapy.

We, together with the Faculty of Medicine at Kumamoto University, are working to establish such testing methods. By establishing these tests with various other treatment methods, we are expanding the scope of these tests not only in Kumamoto, but also in Fukuoka, Saga, Oita, and four prefectures in Shikoku.

The Japan-wide birthrate is declining, and the Administration for Children and Families is eager to expand these inspections, and says that it would probably eventually take the form of a government subsidy. It is precisely because of low birthrate that it is necessary to raise babies that are born in a healthy manner. So, we promote to expand our inspection methods and expand the regions. Even though the birthrate is declining, the 2026 Medium-term Business Plan shows that sales are expected to increase YoY.

During the Kaketsuken period, we were operating this business in the red, but our sales have now grown to about JPY0.7 billion, and we are now in a position to generate a solid profit. We would like to include this kind of treatment method in the future if possible, and we are determined to work on this point in this Medium-term Business Plan.

## Q-4-1-2

By the way, is this a Japan-only business?

#### A-4-1-2

**Nagasato:** Currently, it is only in Japan. We would like to expand this overseas as well, but we test the blood from heels of babies born at obstetrics and gynecology clinics, around five days after birth, by having them put a little blood on a filter paper and sending it to us for testing, so it is a sort of a test with a raw sample.

If the sample is not stored and distributed promptly, the correct data will not be available. So, if we were to expand overseas, our technicians would have to go overseas to do it.

Another issue is whether or not such a system is in place in each of those countries. In the



case of Japan, the system of mass screening has been used for many years since the Showa period, and because of the existence of this system, we have been able to expand new testing methods. I would like to explain where the concept differs considerably from country to country, even overseas.

## Q-5-1

I would like to ask about the NHI price revision. For the past two years, there have been products with positive revisions, and the impact of these revisions seems to have been particularly significant for this year. What is the outlook for future revisions? Looking at the current product mix, there is a reasonable ratio of generics, so should we expect some risk of a negative revision? What is the outlook for NHI price revisions?

#### A-5-1

**Kobayashi:** There are still some antibacterial drugs of specified critical materials that are not yet profitable, so we are asking the government to continue to raise drug prices.

Regarding the overall impact of the drug price revision, generics are certainly at risk of a price revision. On the other hand, fewer product are affected by the NHI price revision as a percentage than other manufacturers, so we think that the average NHI price revision rate will be lower than the average rate.

#### Q-6-1

This is about generic drugs. You mentioned the consortium concept, but please tell us if there are any concrete discussions already underway, what the feasibility is, what the time frame is for realization, and what the performance benefits are.

#### A-6-1

**Kobayashi:** I am now expecting that the consortium concept will probably be written into the Basic Policies for Economic and Fiscal Management and Structural Reform (periodically



released by the Japanese government). There are about 200 companies in the generic drugs business in Japan. About 4,000 products are currently being adjusted for shipment, but this is not due to a lack of manufacturing facilities.

Those companies are controlling sales of many products in small quantities and in small lots. Then there was the NHI price revision, and they were short on staff. We believe that the oversight causes quality problems and does not allow for supply-demand to be managed. I believe that the supply-demand issue will improve if several companies can work together to make effective use of their equipment resources, consolidate a large number of items into a few brands, and create a framework that will be recognized by the government.

That was the premise behind the separation of Meiji Seika Pharmatech Co., Ltd. and Me Pharma Co., Ltd.. If a framework for a stable supply of generic products is established in the country as a whole, we will consider various ways in which our portfolio can be of assistance, and we will negotiate with various companies.

In terms of a time frame, we hope to have a good idea of where we stand this year. I don't know, though, because there is a partner.

## Q-7-1

This is a confirmation of the earlier answer about the KD-414. I believe you mentioned that you have a goal by FY2026, but could you tell us about this again? This is a confirmation of the schedule once again.

## A-7-1

**Nagasato:** We are currently conducting a VE (vaccine efficacy) study in XBB1.5 with a target of 5,000 pediatric cases. It is the first clinical trial in Japan to collect 5,000 pediatric cases, so we are having a very difficult time.

While we manage to do this first, we are discussion with PMDA the next mutant strain, the JN.1 strain. The discussion includes whether to incorporate this JN.1 as well into this VE or just safety.



If we incorporate the next mutant strain into the tests, of course it will take time. I said earlier it would be launched during the 2026 Medium-term Business Plan, but we would like to launch the product on the market as soon as possible, even just a year. The MHLW has been quite active in supporting this. The fact that there has been no progress in vaccinating children, and the fact that whether or not this vaccine, which is domestically produced in Japan, is approved could lead to the next pandemic in the future, so the government is providing us with strong support.

We will do our best to make it to the end of the process, to get approval, and to make it possible to respond to mutant stock one after another.

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