



**SHIONOGI & CO., LTD.**

Meeting of Revision of STS2030

June 1, 2023

# Presentation

---

**Kyokawa:** It is time for us to begin. My name is Kyokawa, Vice President, Corporate Communications. Thank you all very much for joining us today. We will now begin the briefing on the revision of SHIONOGI Transformation Strategy 2030, or STS2030.

First, let me introduce today's speakers. Dr. Isao Teshirogi, PhD, Chief Executive Officer.

**Teshirogi:** Hello. Thank you.

**Kyokawa:** Dr. John Keller, PhD, Senior Executive Officer, Senior Vice President, R&D Supervisory Unit and Vice President, Investment Strategy Department.

**Keller:** Hello. Thank you.

**Kyokawa:** Dr. Toshinobu Iwasaki, PhD, Senior Executive Officer, Senior Vice President, Healthcare Business Supervisory Unit and Pharmaceutical Commercial Division.

**Iwasaki:** Hello. Thank you.

**Kyokawa:** Dr. Koji Hanasaki, PhD, Senior Executive Officer, Senior Vice President, Supply Supervisory Unit and Global Business Division Senior Executive Officer, Supply and Global Business.

**Hanasaki:** Hello. Thank you.

**Kyokawa:** Today, we will present our revision of STS2030, and then we will take your questions. The session is scheduled to end at 17:00. Please note that simultaneous interpretation will be available for today's briefing. To use simultaneous interpretation, please select your preferred language from the screen.

We will now get started. Dr. Teshirogi, over to you.

**Teshirogi:** Teshirogi here. Thank you.

First, I would like to thank you very much for joining us today. As Mr. Kyokawa mentioned, this is a revision, so it is positioned slightly differently from the medium-term management plan itself.

We issued the STS2030 plan exactly three years ago, on June 1. Since then, as I will say later, amidst quite a lot of changes, since the end of last year, the Board of Directors, now mostly from outside the Company, has had at least two meetings, or three if you include off-site meetings. We have had quite a discussion with the outside directors.

We believe that this revision is a significant change and that it will have a very important meaning for our future business activities. We are here today to explain the revision to the outside world.

In addition to discussions with outside directors, we have also had a considerable number of internal discussions, including at management meetings.

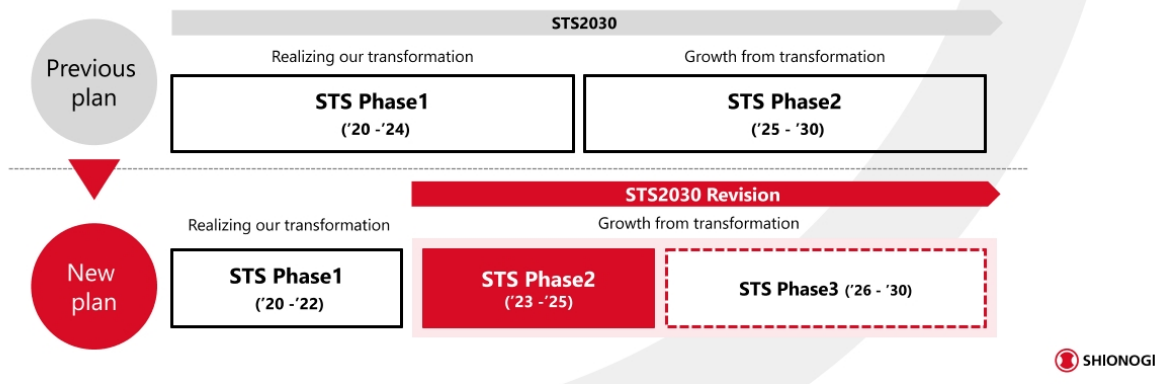
In fact, we have packed this content quite comprehensively. Of course, in relation to the R&D pipeline, we are growing overseas and want to grow further. There is also the question of our approach to investment in R&D, our approach to shareholder returns, and also, our approach to non-financial indicators. We have a fairly comprehensive plan for managing human capital.

I would like to talk about all of these items in detail today. I would also like to consider having a separate dialogue with you about some of the more specific items.

If I were to go through everything page by page today, it would take up a lot of time, so I will just give a general overview today.

## Agenda

1. Reflections on STS Phase 1
2. Road to Realizing STS2030
3. STS Phase 2



2

Please take a look at the agenda page.

We have drawn a conceptual diagram here. We have now reached the end of Phase I of this plan, which spanned the three years from the announcement of STS2030, ahead of schedule. The remaining seven years to 2030 will be considered in two phases.

I would like to focus on Phase II of STS2030, which covers the period from FY2023 to FY2025. I would also like to talk about our thoughts regarding Phase III.

Looking back to this time three years ago, and rereading the presentation materials from then with fresh eyes, we can see what the most important points were then and how they have changed.

At that time, the biggest problem for us was the patent expiry of the oral HIV drug dolutegravir. That is due in 2027 or 2028, with the specific date varying depending on the region.

The biggest thing in our revenue stream is what will happen to HIV royalties, which are likely to decrease a certain amount. In response, we created STS2030 to plan for how to compensate for this and grow even stronger. This was a major theme of the plan.

Not long after initiating our plan, the coronavirus pandemic appeared. For the past three years, we have allocated considerable resources, including R&D, to COVID-19. We have filed for approval for Xocova, or ensitrelvir, in several countries. We have also been able to move forward with vaccines to a certain extent.

In addition, as part of our other activities during this period, we have been selling cefiderocol as an AMR product on a global basis. It achieved sales of more than JPY10 billion in FY2022. Even in the world, there are not many antibiotics with sales exceeding 10 billion yen.

We would like to present our thinking about the next phase against the background of our proven ability to move infectious disease products, especially in the US and Europe, as well as the HIV franchise, our COVID-19 results, and achievements relating to cefiderocol, which continues to make steady progress.

We have increased total assets and strengthened our cash position over the past three years, and I would like to talk about our thoughts for the next stage of growth.

Three years ago, we said, "This is what we want to do," and "we will think about the roadmap as we go along." Now it has become much easier to see the roadmap, and what we need to accomplish. We have also seen a broadening in what we can accomplish. This has led us to the current revision.

## 2030 Vision

Appearance after Vision is realized

- **Continuously creating innovative products/services, with a well-established and rapidly-growing global business**
  - Expansion of business model
  - Maintenance of high profit margins and growth after overcoming the patent cliff
- **Continuing to offer solutions to health issues facing society**
  - Freedom from the threat of infectious diseases, better QOL, extension of healthy lifespans, contribution to sustainable social security, and contribution to achieving SDGs
- **Excellent business persons who never take a break from building their expertise and capabilities, leveraging their individual strengths and creating new value**

4

SHIONOGI

Now, I would like to talk a little bit about this. Page four, please.

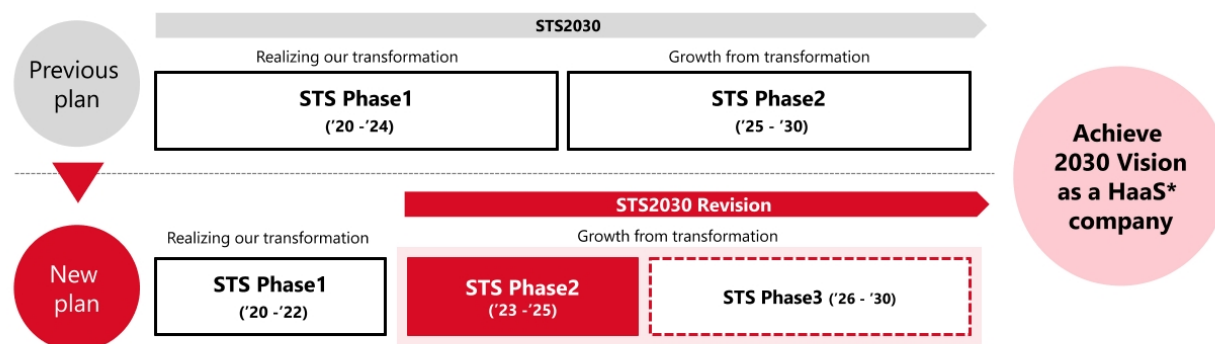
Here, I am making a point of using the same slide that we used three years ago. This is the kind of company we want to be in 2030. Our vision for 2030 is unchanged. Our thoughts back then have not significantly changed, and looking back at them now, do not appear to have been mistaken.

However, the coronavirus pandemic plunged the world into confusion, and what we want to do and what we need to do is becoming clearer. With Dr. Keller in his post for about a year now, our approach to R&D has changed considerably. We have shifted from the pipeline approach we had been using to an approach based on unmet needs, which takes advantage of our strengths. Our theme is to develop these products on a global scale, covered by Dr. Iwasaki and Dr. Hanasaki, and to sell them and generate sales on our own. Looking forward to 2030, our destination has not changed, but where to concentrate our attention has changed.

In order to build on this, people, organization, and culture are all important. We have been thinking about how to create excellent business talent and how to streamline the Company's decision-making process.

## Purpose of the STS Revision

- **Significant progress toward achieving the 2030 Vision was made over the first three years of STS Phase 1**  
 ⇒ **The road to achieving the 2030 Vision has become clearer**
- **Initiating a new growth phase in STS Phase 2, raising financial targets**



5

\* Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only providing pharmaceuticals



As I explained earlier, the purpose of this revision is to divide the seven-year period into two parts, and to present a package of what Phase II of STS2030 will target and an outline of Phase III.

## Reflections on STS Phase 1: Main Achievements

Expansion of products discovered internally		Achievement of major KPIs			
<ul style="list-style-type: none"> <li>• <b>Obtained domestic approval of ensitrelvir for COVID-19 treatment</b></li> <li>• <b>Strengthened overseas business</b> <ul style="list-style-type: none"> <li>- Growth of cefiderocol; GARDP<sup>*1</sup>/CHAI<sup>*2</sup> framework with MPP<sup>*3</sup></li> </ul> </li> <li>• <b>Achieved growth of the HIV franchise</b></li> </ul>		(STS2030 target value in parenthesis)			
<b>Launch of products and services other than prescription drugs</b> <ul style="list-style-type: none"> <li>• <b>Filed application for domestic approval of COVID-19 vaccine</b></li> <li>• <b>Provided new products and services in the infectious disease and CNS areas</b> <ul style="list-style-type: none"> <li>- Wastewater surveillance service (AdvanSentinel), educational support (Yui Connection), brain activation by sound stimulus (kikippa), insomnia treatment app (SUSMED Med CBT-i<sup>®</sup>)</li> </ul> </li> </ul>		<b>KPI</b>	FY2020	FY2021	FY2022
<b>Growth</b>	<b>Revenue</b>	297.2 B yen	335.1 B yen	426.7 B yen (400.0 B yen)	
	<b>Core operating profit<sup>*4</sup></b>	94.0 B yen	110.6 B yen	158.5 B yen (120.0 B yen)	
	<b>Core operating Profit margin</b>	31.6%	33.0%	37.1% (over 30%)	
	<b>Overseas sales ratio</b>	16.2%	22.3%	16.9% (over 25%)	
<b>Shareholder return</b>	<b>Original pipeline ratio</b>	71%	73%	61% (over 60%)	
	<b>EPS</b>	365 yen	378 yen	619 yen (over 370 yen)	
	<b>DOE</b>	4.1%	3.8%	3.9% (over 4%)	
	<b>ROE</b>	13.9%	12.5%	17.8% (over 13%)	

6

<sup>\*1</sup> The Global Antibiotic Research and Development Partnership <sup>\*2</sup> Clinton Health Access Initiative <sup>\*3</sup> The Medicines Patent Pool <sup>\*4</sup> Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)



Here are the main results of Phase I, the first three years of STS2030.

Regarding the expansion of our in-house products, as I mentioned earlier, the second one from the top, it may be an exaggeration to say that we have led cefiderocol to complete success as an overseas business, but at least we have surpassed the first threshold of JPY10 billion in sales. I think we can claim a certain amount of credit for that.

In order to develop Xocova, cefiderocol, future infectious disease drugs, and so on, we have started collaboration with GARDP and CHAI for cefiderocol, and with MPP for ensitrelvir, which we could not do with Xofluz. In fact, these two collaborations have been progressing very concretely. We are now in the phase of nominating sublicensing companies.

We originally thought the big date for the HIV franchise was 2027 or 2028. Some variability is expected in the results, but we believe that it will remain stable until approximately 2040. We can say that the 2027/2028 point is no longer an issue for us. Rather, we believe that now that we have a solid base, we can focus on how to build on that.

As for COVID-19, we believe that we will be able to obtain approval for a vaccine as well as Xocova, as I mentioned at the last financial results meeting. We have also taken a step forward with our own HaaS, such as planning wastewater-based epidemiology surveillance service, support for school attendance, and, although still in the OTC area, we have partnered with a venture company on gamma wave sounds that may have positive effects on dementia.

We seek to address the issues facing patients and society by transforming ourselves from a pharmaceutical company that provides only ethical drugs to “a healthcare provider” that provides comprehensive healthcare services and continuously offers new value to society. We think we were able to take at least one step towards those. As I will explain later, by reorganizing the organization into four broad areas of jurisdiction, we were clarifying where the responsibility for business execution lies and further accelerating decision-making.

We believe that we have made great strides in management to improve both the speed and quality of decision making.

We will now talk figures. The figures for FY2022 on the right have already been announced. We can compare these with the figures for FY2020, which were announced exactly three years ago. Apart from this JPY420 billion figure for sales, the other figures, including core operating profit, core operating margin, in-house drug discovery ratio, EPS, ROE, have already exceeded the forecasts for FY2024 and FY2025 that were announced at that time.

As you will see later, the figure for core operating profit was JPY150 billion, for core operating margin 30% or more, for in-house drug discovery ratio 60% or more, for EPS JPY480 or more, and for ROE 15% or more. This has already been accomplished two years early.

With this in mind, we feel it is best to not continue with the original Phase I of STS2030, and instead revise the plan with new targets, both internally and publicly.

# Reflections on STS Phase 1: Learnings and Points to Strengthen toward Transformation

## Lessons from the COVID-19 experience

### Renewed recognition of the threat of infectious diseases

- The impact of COVID-19 on the world

### Importance of the discovery of drugs for unmet needs

- Therapeutic and vaccine R&D efforts for COVID-19 were supported by many stakeholders

### Lack of ability to deliver globally

- Lack of global sales and supply capabilities

### Importance of business speed

- The speed of COVID-19 drug discovery will become the standard



## Recognition of the lack of capability to respond quickly to changes in the business environment

## Points to strengthen toward transformation

### Marketing capabilities –Ability to deliver globally–

- Develop a global marketing system; strengthen supply chains
- Develop sales routes for products and services other than prescription drugs

### Pipeline –Investment in unmet needs–

- Invest in R&D, shifting resources flexibly to highest priorities/best opportunities
- Invest aggressively to acquire growth drivers

### Strengthen company platform –Improve business speed; strengthen human resources–

- Making and implementing decisions: Improve speed in all aspects
- Revise/reinforce the necessary capabilities
  - Develop current human resources; hire outside personnel

Once again, I would like to take this opportunity to review Phase I.

We do not mean to suggest that everything went well. During the coronavirus pandemic, at peak we invested nearly 80% of our internal resources in COVID-19-related projects. Although we have been criticized for our lack of speed compared to overseas companies, we still managed to find seeds of innovation and then create products, develop them, and deliver them to the market faster than we have ever done in our history.

What we need to do now is to evolve into a company that is capable of doing this for any project, not just under special circumstances like the coronavirus pandemic. I think this is very important. By focusing precisely on unmet medical needs, we can gain a lot of external support and focus on specific goals.

We are truly strong when we identify an unmet need and the Company comes together to address it. We also receive support from society. Conversely, it was an important experience for our company to see what it would be like to interact with society in the future if we were to develop products that do not meet unmet needs.

As We mentioned earlier, we have teamed up with GARDP, CHAI, and MPP for the first time to start delivering products globally. We are still inferior to other companies in terms of some procedures and securing sales. We are aware of this as well, so we are wondering how to fix this in the next three years. The theme of today's meeting is laying out that plan.

Turning to the other speakers today, Dr. Iwasaki and Dr. Hanasaki are focused on selling globally, and Dr. Keller is more determined than ever to research and develop products that will meet unmet needs.

To this end, we are trying to think of new ways to form alliances internally, and at the same time, to include people from academia within the Company. And as for the foundation of the Company, I am wondering how we can improve speed and quality, the two most important factors.

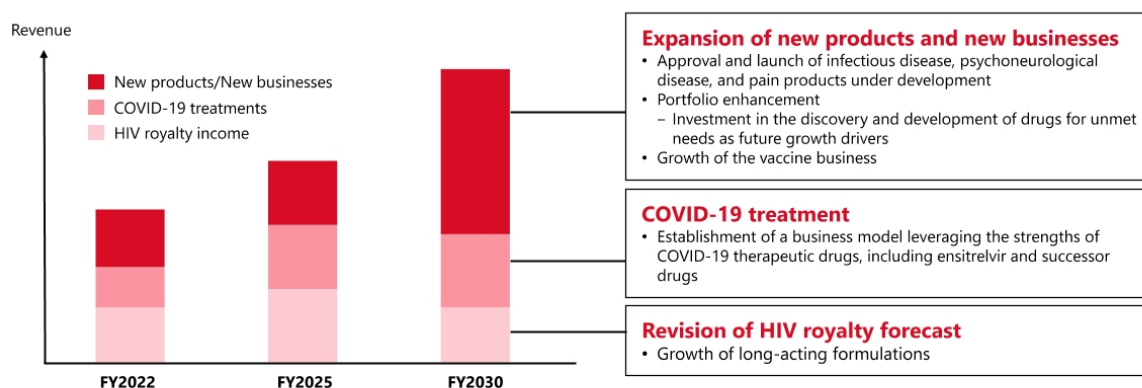
We've always said that in our company, the key words are transparency and traceability. In any case, we can make decisions with a high degree of transparency and then properly follow up on the decisions we have made, and we can trace them. If these two things are in place, shareholders and other stakeholders will trust

us to manage the Company. We believe that opaqueness and lack of traceability are the biggest reasons for the loss of trust in our company, and we have changed our internal decision-making structure considerably as a result.

I would like to start with the three pillars of the revision for Phase II.

## STS2030 Revision: New Growth to Realize the 2030 Vision

- **Continued growth of HIV franchise**
- **Growth centered around ensitrelvir (STS Phase 2: 2023-25)**
- **Growth toward realizing the 2030 Vision through aggressive investment (R&D, business investments) (-2030)**



9



Please continue to page nine.

This is a schematic diagram of what must be done over the next three years, which are very important as we aim for our 2030 Vision. The slide also outlines what must be done for the four years beyond that.

The right-hand side of the chart shows our vision of where we want to be in 2030, and as I will explain later, we do not believe that infectious diseases, COVID-19, or acute respiratory infections, whether they are coronary or influenza infections, will disappear that easily on a global scale.

In this context, we have both, whether it is influenza or COVID-19 solutions, and we also have vaccines, which are certain new products. We are going to make significant growth globally in the field of infectious diseases. This is very important.

As for the HIV business, of course ViiV is the main distributor, but how do we evaluate and support the long-acting injectable drug that ViiV is planning to develop from a research perspective?

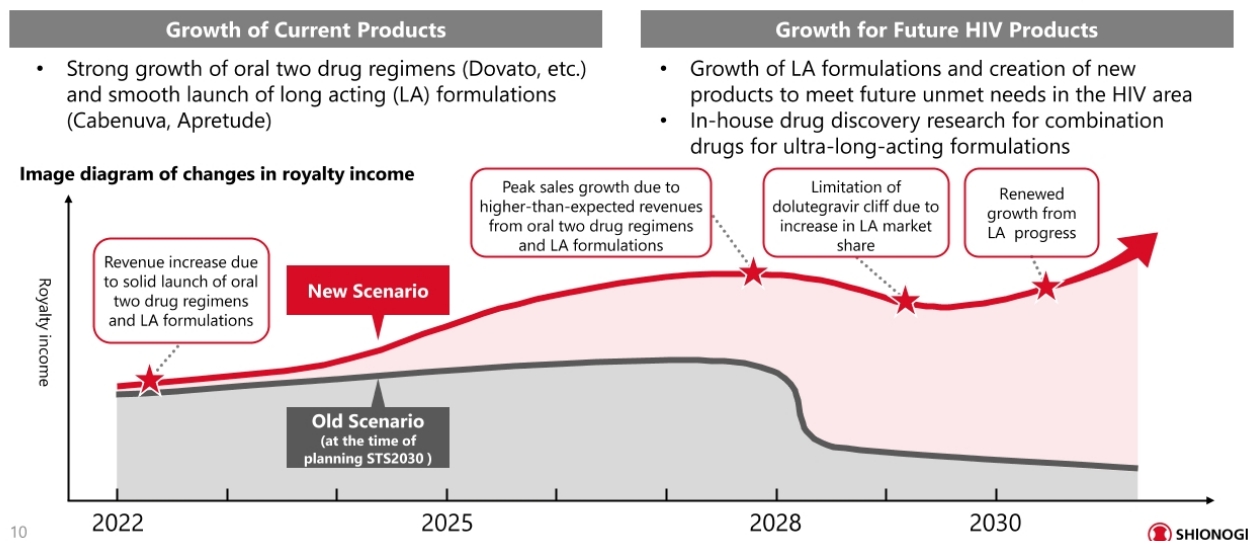
Consider also newer oral drugs, for example. Our competitor, Gilead or Merck is now doing something like a once-a-week oral drug. We would like to support such research, including the question of whether a new mechanism of action, such as a once-a-week oral drug, should be considered.

We would like to reinforce and support the HIV business and create a revenue stream that will allow people to view the royalty stream I mentioned earlier with peace of mind.



## Current State and Future Outlook of the HIV Business

Continued growth will be achieved through the continuous introduction of products that meet patients' needs



First of all, there is HIV.

New data is being released every day, including scientific data, sales data, and data on how patients and doctors are perceiving our products.

For us, certainly in 2028 or 2029, there may be a little bit of a drop due to the loss of intellectual property for oral drugs, but from the royalty stream that will grow at least all the way from now to 2025, 2026, and 2027, we will aim at that time to be at the 2025 or 2026 level. It probably won't drop below that level.

Moreover, our best estimate is that this will continue until about 2040, so I believe that we can now feel quite secure in terms of our support.

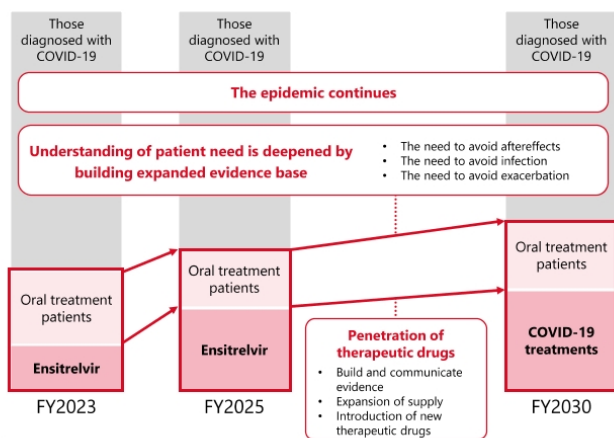
Of course, we are paid in British pounds, so if the yen appreciates to an unbelievable and unthinkable level, our royalties may look a little low in yen terms. However, when considered on a local currency basis, we believe that the level of royalties will be around the level shown here.

As I mentioned earlier, this is one of the biggest changes since we announced STS2030 three years ago. I believe this will allow us to grow our company by increasing our in-house sales. Where we used to think that there would be some fallout that we would have to fill in, we now see it as a phase where we will have peace of mind that in-house sales will directly contribute to growth for the Company. I believe this is a very important point of this revision.

# Actions and Outlook for COVID-19 treatments

## Prediction and direction for COVID-19

- Our prediction: The epidemic continues as the virus evades immunity while continuing to mutate
- Our direction: Establish a position as the global standard COVID-19 drug based on clinical evidence



## Actions for continuous growth of COVID-19 treatments

- **Offer new evidence of ensitrelvir’s value**
  - High-risk outpatients, in-patients
  - Evidence of disease prevention, reduce risk of long COVID, etc.
- **Provide ensitrelvir globally**
  - Asia: File application for approval in East Asian countries and expand to ASEAN\* countries
  - U.S., Europe: Approval and launch from FY2024
  - Other areas: Swift supply planned through partnering
- **Discover even more convenient new therapeutic drugs such as S-892216**

As for COVID-19, as you can see at the top, I believe that it will continue to be a factor to a certain extent.

For example, a doctor at the National Institute of Infectious Diseases says that although the number of patients with mild symptoms has increased since the Omicron strain was identified, the persistence of neutralizing antibodies after infection or vaccination has clearly shortened. After roughly three months to four months, the level of neutralizing antibodies has dropped considerably.

This is true whether it is messenger RNA, recombinant protein such as ours, or possibly inactivated, but the level tends to be constant. Of course, the length of time varies a little depending on the modality and the product, but the neutralizing antibodies fall off at a certain speed.

Therefore, we believe that it is very difficult to completely control infection and disease outbreaks. Of course, for influenza, we thought there would be more movement last winter, after three years of very low infection numbers, but it was not that big a wave.

However, in May and June, influenza broke out in many places. Infectious disease specialists do not like the fact that trends relating to the avian flu and other influenza strains are moving much faster and much bigger than before. We have neuraminidase and Xofluza, cap endonuclease, so how can we prepare well and prevent the next pandemic?

As you are probably aware, the surface antigen mutation itself is much faster in influenza than in COVID-19. Influenza mutates very quickly, but so far, because there has been no human movement and no animal movement, mutation has not reduced its toxicity or immunosuppressive properties.

What we experienced with COVID-19 is that when people move that fast globally, even surface antigen mutations like COVID-19 mutate quickly. In the case of influenza, which is a highly virulent virus that can cause considerable problems, we believe that the provision of both therapeutic drugs and vaccines, including both COVID-19 and influenza, is in line with the needs of the world.

With that said, let's start with ensitrelvir. We hope to achieve a certain level of sales this year in Japan and other Asian countries. In the next fiscal year, we expect to sell our products in a wider range of places,

including the United States and Europe. We are well aware of drug-drug interactions and the effects on pregnant women.

In some cases, it may be better to use something a little more convenient. For example, S-892216. We are not thinking of that right now, but if you think about Xofluza, it is one treatment. Originally, Tamiflu was twice a day for five days, but we were able to create a very convenient treatment with a single dose. We would like to ensure a certain amount of sales by continuing this on an ongoing basis, while considering feasibility in the future.

Next is slide 12.

We have talked about HIV and the drugs we use to treat it, including ensitrelvir. The table here shows what else is going on.

In particular, the left side of the table above shows the products to be launched and sold by FY2025, which are mainly licensed-in products or those sold in Japan. The right side shows products that we expect to launch and sell as early as possible after FY2026.

While growing these new products, we are also working on Xofluza and cefiderocol, which I mentioned earlier, and naldemedine, which is now being promoted in Japan under Dr. Iwasaki. We are thinking of doing this in China as well, and the medium-term plan includes the expansion of new products, including these types of products.

We have made detailed sales figures for each product, including vaccines, for each geography, and we have set sales targets based on these figures.

We have been following the detailed figures of when, what kind of approval, and how much of the product will be sold in Japan. We have been following the figures in great detail.

At the bottom of this page are vaccines and OTC medications. It may seem modest, but even just for OTC in Japan alone, we have achieved the highest sales for four consecutive years and have risen more than 10 points in the industry ranking. We are also recording record profits. Strictly speaking, we have this OTC under the umbrella of Ping An Shionogi. We are thinking of expanding this OTC to Asia, in conjunction with other products.

## Revise Major KPIs (key evaluation indicators)

- Revised revenue forecast for FY2030 (600.0 B yen ⇒ 800.0 B yen) due to business growth through expansion of global sales of ensitrelvir and HIV pipeline/aggressive investment
- To promote aggressive strategic investment, adjusted one of the profit indicators from core operating profit to EBITDA\*
- Incorporate non-financial indicators centered on the environment, human rights, and human capital\*2

	STS Phase1	STS Phase2		STS Phase3
	FY2022	FY2023	FY2025	FY2030
Revenue	<b>426.7 B yen</b>	<b>450.0 B yen</b>	<b>550.0 B yen</b>	<b>800.0 B yen</b>
Overseas sales CAGR*3	—	—	<b>50%</b> Starting from FY2022	<b>15%</b> Starting from FY2025
EBITDA	<b>177.9 B yen</b>	<b>167.0 B yen</b>	<b>200.0 B yen</b>	—

13

\* EBITDA(Earnings Before Interest, Taxes, Depreciation, and Amortization)  
\*2 Described on pages 29 and 30 \*3 CAGR(Compound Annual Growth Rate)



As for KPIs, of course, we naturally have detailed figures for all of them. People may well say, "Shionogi originally focused on operating profit and operating margin, so they will continue to do so," but this time, we would like to put forth these three as our most important KPIs.

As for the figures for the current fiscal year, we have already presented them as this year's business plan. The forecast for FY25, ending March 31, 2026, shows sales revenue of JPY550 billion, overseas growth rate of 50% excluding royalties, and EBITDA of JPY200 billion.

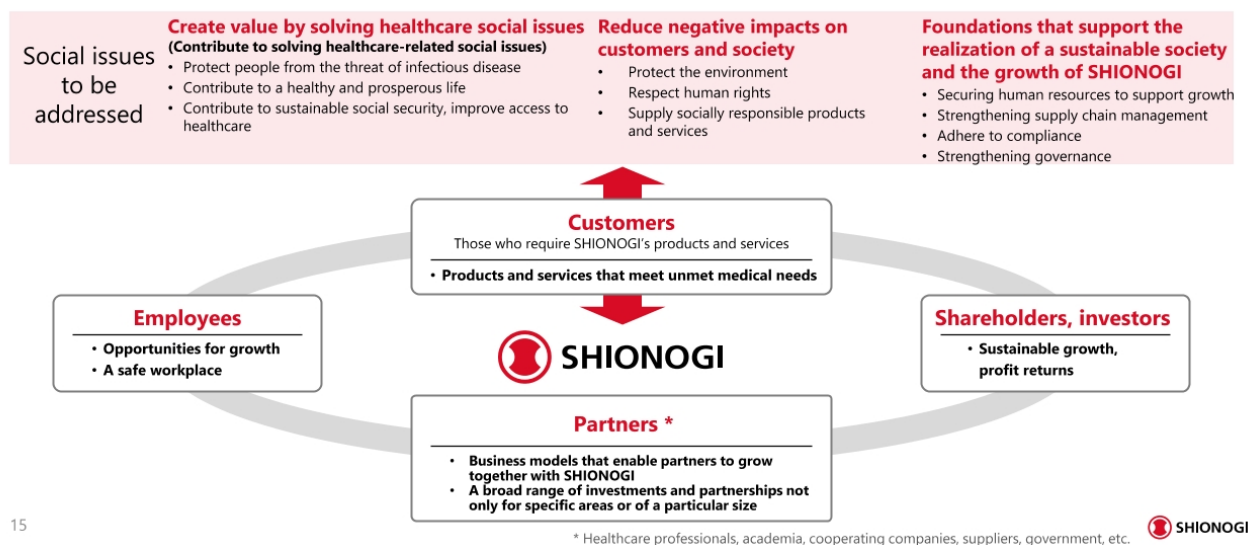
This is from the figures we have accumulated, which I mentioned earlier. We are a little conservative here. You may say, "Isn't this too low?" However, we would like to start from there, as it is the way we have been presenting our business plan so far, and we would like to exceed this level.

The forecast for FY2030 is JPY800 billion in sales, a JPY200 billion increase over the forecast we gave you three years ago. How do we develop and advance HIV drugs, infectious disease drugs, vaccines, and these kinds of things? As we are considering selling in-house globally, we would like to set our own target at JPY800 billion, an increase of JPY200 billion above this figure, as the figure we have subtracted ourselves.

Naturally, when we consider that we are going to sell JPY800 billion, I am sure that your model will give you a good idea of how much operating profit we can expect to generate. We are proud that we have a very strong corporate structure in terms of generating operating profit. We would like to move forward with the goal of achieving JPY800 billion in sales as our primary internal target.

# Value Provided to Stakeholders

As a HaaS company, collaborate with stakeholders to contribute to solving healthcare-related social issues



15



Now, let me go into the contents of Phase II for a moment.

The first is on page 15. I am writing this in the context of the value we provide to our stakeholders.

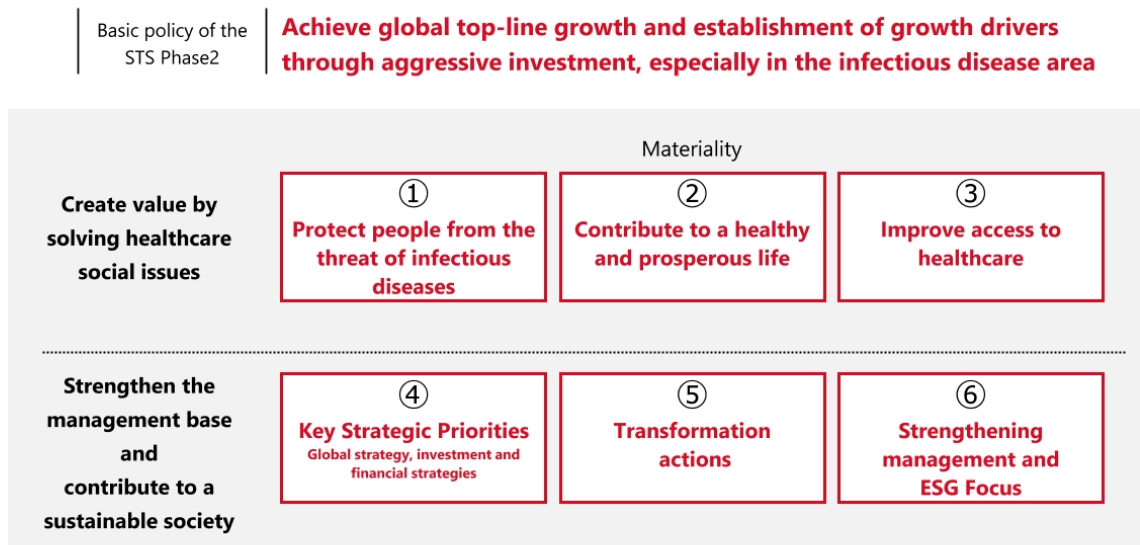
In terms of materiality, or the social issues that we need to address, as you can see in the pink section above, we will continue to provide value with respect to, above all, infectious diseases. I will go into some detail about unmet needs later, but I would like to reiterate that when we think about society and the world in 2030 or 2040, we would like to think about what we can offer and how to create new value for our customers and society.

We also want to contribute to a sustainable society. I will later provide some examples of non-financial indicators, including both quantifiable and non-quantifiable ones. We are discussing these in detail at Board meetings, and will continue to do so.

Given the speed with which we developed Xocova, how fast can we take the R&D timeline we achieved there and apply it to other drugs? This is our most important theme for the next three years.

It is important to strengthen the management foundation. How did we develop Xocova so fast? It's because we made solid, "go or no go" decisions quickly. We are also considering how we can strengthen compliance, and how we can strengthen DE&I and its governance.

## Overview of STS Phase2



16



We have divided these into six elements for easier understanding, which I will explain on the next page and thereafter.

Rewriting the pink part on the previous page as basic policy, there are two major frames.

Sell globally, mainly in the infectious disease area. This is the first major theme.

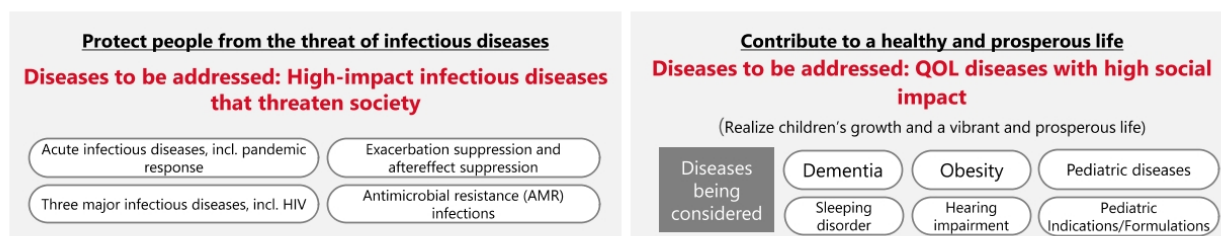
The second theme is how to develop the cash balance we have today, including R&D and possibly M&A, into the future. We are using EBITDA as a KPI. The reason why EBITDA is used instead of operating profit or operating margin is that EBITDA is more important for our own mentality to make decisive decisions for future growth, including investment.

I would like to explain one by one about these points. The top three are infectious diseases, contribution to a healthy and prosperous life including new unmet medical needs, and improvement of access to healthcare.

# Healthcare-related Social Issues Addressed by SHIONOGI

## Work to address unmet needs to protect people from the threat of infectious diseases and “to contribute to a healthy and prosperous life

<b>SHIONOGI's idea of unmet needs</b>	<ul style="list-style-type: none"> <li>Healthcare issues and diseases that are expected to remain unsolved and increase over the next 10–20 years</li> <li>Issues and diseases for which the best solutions can be realized by combining SHIONOGI's strengths and external networks</li> </ul>
<b>Select focus needs</b>	<ul style="list-style-type: none"> <li>The needs to be addressed are decided by management and addressed by R&amp;D's high execution capability</li> <li>Break away from full in-house development to search for seeds and technologies and build networks worldwide</li> </ul>
<b>Concentrate resources</b>	<ul style="list-style-type: none"> <li>Implement bold resource allocations learned from COVID-19</li> </ul>



This is our own idea of materiality and what we consider as unmet needs.

We had a lot of internal discussions on these matters, including with young aces in their 20s and 30s. We have included in this document our vision of what kind of company we want to be and what kind of things we want to do.

Naturally, with the threat of infectious disease, the coronavirus pandemic, which brought so much fear, was the kind of event we had been waiting for. It was very rewarding for our company and our employees to respond to the needs of society. Having experienced that, I want to do a job where we can work equally well with infectious diseases and other things.

So, especially on the right side, infection is not that different from the previous extension, which I will explain later. The right-hand side of the chart shows the six areas where we want to contribute to a healthy and prosperous life, and in particular, the six areas that we are currently considering as major themes for the Company. We would like to be a company that can contribute in these areas by combining our drug discovery capabilities with our outside network.

The area of pediatrics in particular is of great importance to us. As a matter of detail, there is an old infectious disease drug called BAKTAR. This is one of the drugs that should be used when a child has a very intractable infection. It has been used for a long time and is a very large pill. These are pills that are not suitable for children to take. The doctors at the Maternal and Child Health Center asked me if this could be done in smaller tablets. We were asked if we could make it into something that children could take, so we created BAKTAR Mini tablets.

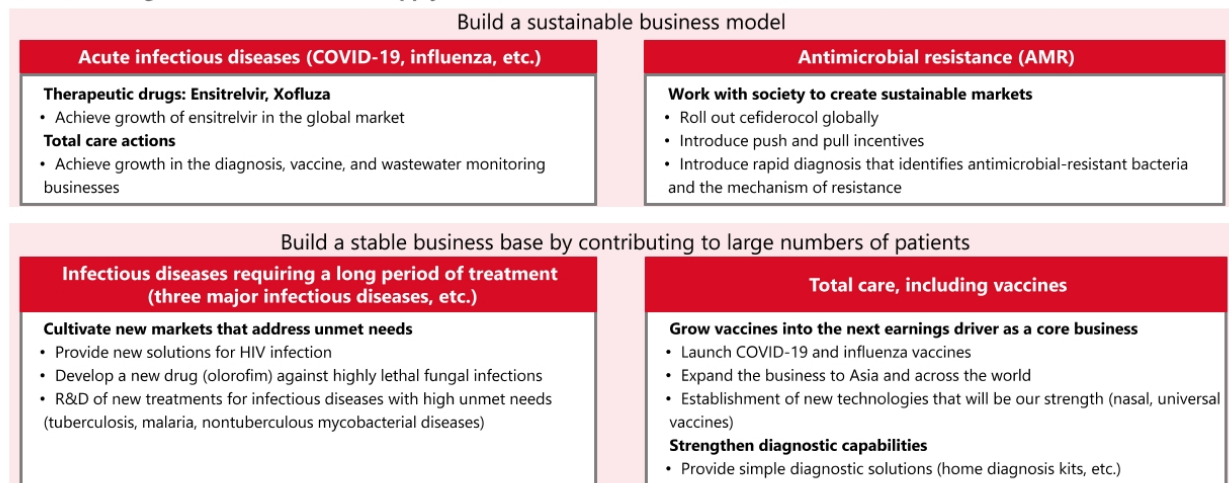
To be honest, it is not that much money, but I can't tell you how many clinicians have thanked me for my work. It is great for us to hear people say, "having these things available means we can raise our children with peace of mind." I would like to make a more proactive effort as a company, including the development of new formulations, and this is mentioned here.

Create value by solving social issues: ①Protect people from the threat of infectious diseases

## Strategies for the Infectious Disease Business

**Establish a business model for each area to achieve continuous growth**

**Contribute to global health and stable supply**



18



Next, infectious diseases. I am sure that the media and analysts present here will broadly agree with what we want to do.

As for acute infectious diseases, we have begun clinical trials for RSV, and for oral drugs. This is a commitment that we intend to continue.

The AMR issue is listed on the right. We have achieved some results with cefiderocol, but this remains a major issue, with pull-type incentives available. There are many ventures and venture companies that have created good products but are having real problems getting approval and then not being able to do business.

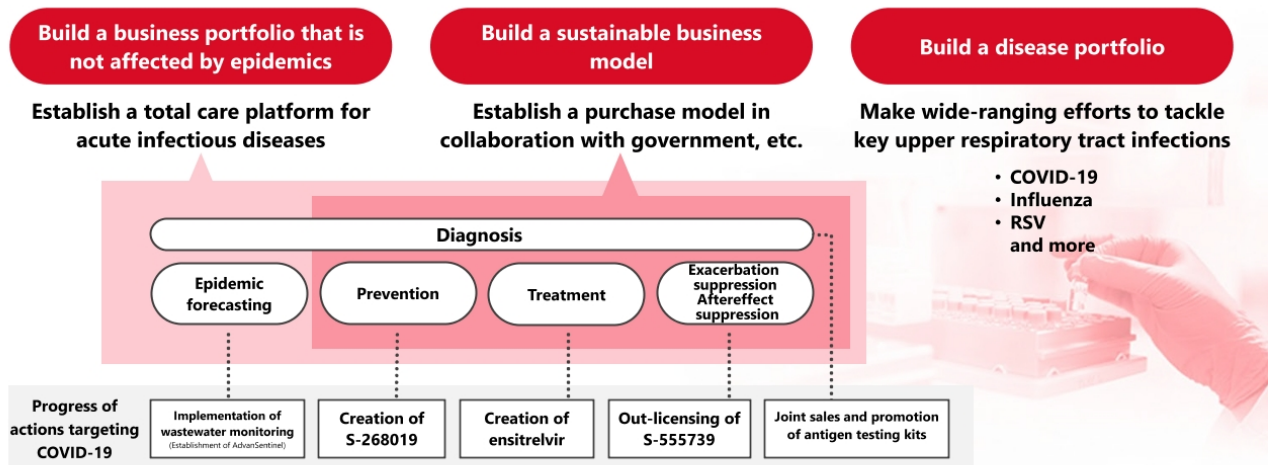
If this model does not work, after all, even a specialized infectious disease manufacturer like us will not be able to produce AMR compounds. We may be forced to stop making them. Our goal is not to make money, but to save humanity from a silent pandemic. We would like to tackle this problem, which is killing about 2 million people every year.

We also want to address high unmet need for infectious diseases that require long-term treatment, such as HIV, tuberculosis, and malaria. In the past three years, we have deepened our confidence in the vaccine area too, and we would like to continue to promote this area. We hope to sell more than 100 billion vaccines globally as a business by FY2030.



Create value by solving social issues: ①Protect people from the threat of infectious diseases  
**Global Rollout of Acute Infectious Disease Platforms**

**Offer total care globally that goes beyond medicines building a sustainable business model**



As for acute infections, as you have seen, the bottom of this page shows what we have done and learned, with COVID-19 as an example.

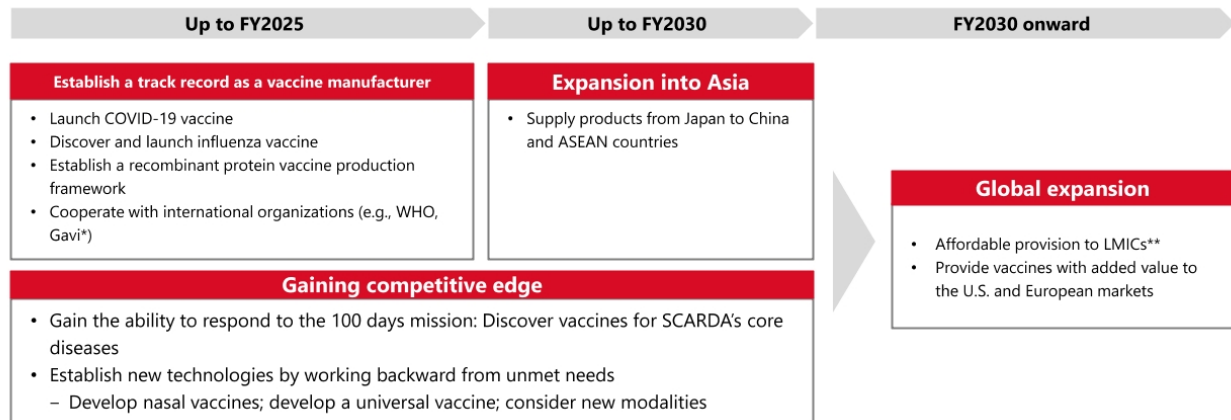
I believe that the ability to predict epidemics, control severe disease, and properly diagnose each step of the process is absolutely necessary to save the lives of people suffering from infectious diseases. Thinking in this way, we do not have to do everything ourselves, and we would like to find top partners to work with.

With regard to infections that require a long period of treatment, such as those that are considered chronic infections, we would like to continue to see if these five boxes are filled properly. This business cannot continue unless we can generate a certain level of sales and profits, even when a disease is not in an epidemic.

Create value by solving social issues: ①Protect people from the threat of infectious diseases

## Actions and Outlook for the Vaccine Business

**Aiming to grow the business into the next earnings driver, offering a steady business model less affected by patent cliffs**



20

\* Global Alliance for Vaccines and Immunization \*\* Lower Middle Income Countries



Next, vaccines.

First of all, as you can see on the upper left, we would like to strengthen and solidify our production system while marketing the COVID vaccine after receiving approval for S-268019. We have already started dialogue with international organizations such as the WHO and Gavi. We would like to deliver these products from Japan to Asia.

While vaccines are a new area for us, that does not mean we have not worked on infectious diseases or researched immunology. I think that we have made considerable progress in nasal vaccines, or universal vaccines, while advancing this S-268019. The first thing we would like to do is to offer it, but after that, we would like to proceed with nasal or universal vaccines and ask if we can create something unique that is Shionogi's style.

In fact, we have already started a dialogue not only with the Japanese government, but also with the US and European governments on how to prepare for the next pandemic. Shionogi's unique technology in this area will allow us to show everyone, especially around the R&D Day, that we have come up with an interesting new vaccine.

Next is slide 21.

Here, we have carefully described each item in the picture I have just presented on page 12, saying that they can be placed on the market by FY2025.

Resiniferatoxin was described in a recent press release. Our partner, Grünenthal, has received breakthrough therapy approval from the US FDA, and we are very excited about it.

It is painful, but by giving this toxin, we are really seeing patients whose pain disappears after about a week. We believe that there is a very large market for this product, especially in Japan where the population is aging.

As I mentioned when we announced our financial results, I believe that zuranolone is one of the compounds that we have the highest expectations for, including our partner Sage and its parent company, Biogen. We will soon receive the final Phase III results in Japan. With these results, we would like to bring the product to market as soon as possible and deliver it to patients in Japan as soon as possible, especially given its immediate efficacy.

We are also working on Phase III of BPN14770 for Fragile X. Also, we are aiming for further expansion for Symproic, or naldemedine.

Create value by solving social issues: ③Improve access to healthcare

## Actions to Improve Access to Healthcare

**Delivering the necessary solutions (drugs and services) at the necessary time through various initiatives to improve access to medical care**

### Actions to protect people from the threat of infectious diseases

#### Improve access to LMICs

- Collaboration with GARDP/CHAI
- Collaboration with Medicines Patent Pool
- Listing on WHO Model List of Essential Medicines\*

#### Promote and raise awareness of the proper use of infectious disease treatments

- In cooperation with and with support from ministries of health and experts in each country
- Holding educational seminars and practical classes for the general public

### Actions to contribute to a healthy and prosperous life

#### Address problems that cannot be solved with medicine

- Supporting children with developmental disorders in communities, schools, and workplaces
- Provision of educational support system (Yui-EN)
- Supporting mother and child public health in Africa
- Elimination of communication barriers due to individual characteristics

**Mother to Mother**  
SHIONOGI Project



Improved access to healthcare.

This is really a steady activity, especially for our young employees, but I am quite proud of this activity. I believe that we are doing a good activities that are different from other pharmaceutical companies. We have talked about GARDP, CHAI and MPP in the context of improving access to LMICs.

In particular, the part on the right is about neurodiversity, as represented by ADHD, for example. We would like to help support children's futures, as well as supporting the people around them. We have been working steadily to find ways to address this issue.

Our support in Africa, Mother to Mother, is already in its third phase, which spans more than 10 years.

Then there are communication barriers. This activity is also difficult to put into words, but some of our employee have difficulty processing information, so for example, when they go to the doctor to have their medication explained to them, they are unable to understand it. We have been working quite diligently, mainly at hospitals, to prevent accidents that could result from taking the wrong medication or using it incorrectly.

We call this activity "communication barrier-free,". I think it is making a very significant contribution to society in terms of what a pharmaceutical company like ours can do. We will continue to do this as a strengthening project in the next phase.

Strengthen the management base and Contribute to a sustainable society

## Building a Foundation for Realizing New Value Creation

Basic policy for building the management base

**Create value by transforming our structure, changing the process that moves the structure, and developing human resources that can operate the process**



23



From here, I have written a summary of ④, ⑤, and ⑥, the strategies we will focus on to build the foundation, our efforts for change, and what we will evolve as ESG management.

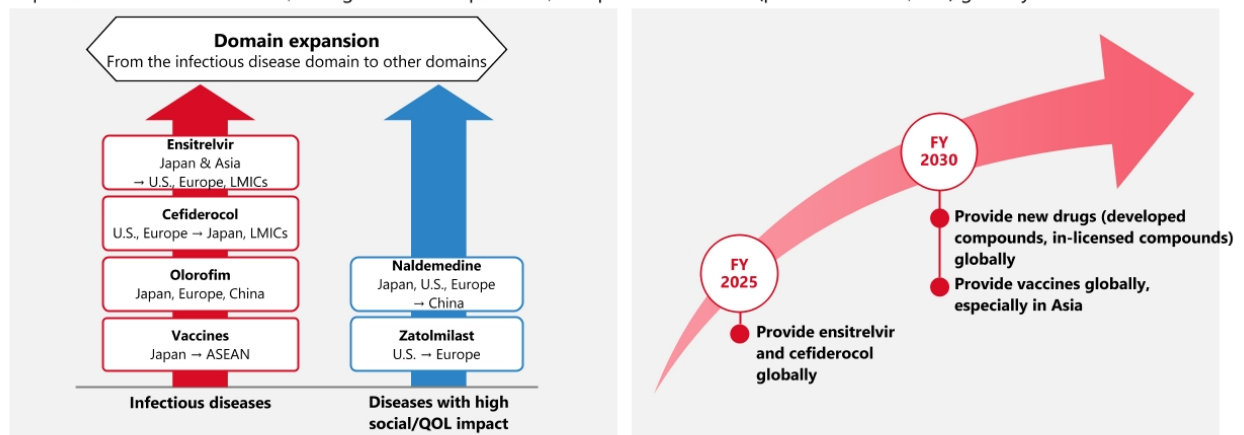
As a base, we are writing about how to create an organization that is as highly productive and speedy as possible.

Strengthen the management base and Contribute to a sustainable society: ④Key Strategic Priorities

## Acceleration of Global Expansion

**“Supply the best and necessary medicine globally” based on the SHIONOGI Group Heritage (the company policy of SHIONOGI)**

Improve access to medical care, strengthen sales capabilities, and provide solutions (pharmaceuticals, etc.) globally



24



The first is global expansion.

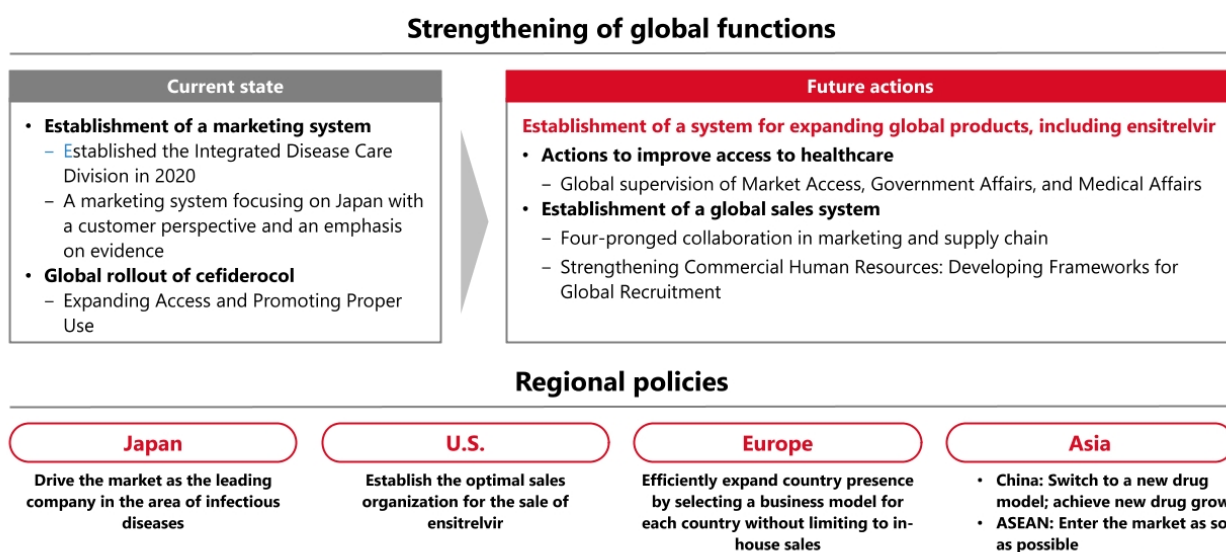
On the left side, we have a lineup of infectious disease drugs, and I think you can see that we have a pretty clear idea of what we are going to do. As for Fragile X and naldemedine, which I mentioned earlier, we are just getting started.

This is under Dr. Keller, and we would like to move forward with both compounds that meet our new unmet needs that are coming out now, and the results of our research and development, which will increase on the light pink side here. In order to achieve this, we are now talking about how to go about this on a global scale, which is a very high priority within the Company.

Our Vice Chairperson of the Board, Ms. Sawada says, "The head office is the least globalized, so we need to globalize the head office." We are now seriously discussing how to proceed with this, including organizational reform, as soon as possible.

Strengthen the management base and Contribute to a sustainable society: ④Key Strategic Priorities

## Strengthening of Global Sales Capabilities



As for globalization, we have set ourselves a goal that is within our own size, but with a considerable stretch.

With regard to expanding overseas, investors asked me, "So you are buying distributors in both the US and Europe?" We have been asked if we are going to make a very large investment, but we do not intend to do so at this time.

To tell the story a little more concisely, when we were supplying Xofluza to Roche, we could have done it ourselves if we did not have such a large sales organization in the hospital field or other areas. At that time, the primary care market for influenza drugs was very large, and we might need several thousand sales representatives for that alone.

As expected, at our size, we could not hire 3,000 people for a single item, so we asked Roche to do most of the work, although we are in charge of one part of the hospital area. However, I believe that we have achieved a certain level of success by ourselves in doing hospital-centered promotion for AMR, like cefiderocol.

We would like to think globally about how we can lead to success by steadily working on what we can do and accumulating good experiences. In the US, when we sell ensitrelvir, there are two parts: some we do ourselves, and for some we hire, for example, a CSO. In Europe, we are now looking at what to do with Rizmoic

for each country in detail in Europe, and we are doing it in line with reality, such as Spain like this and Eastern Europe.

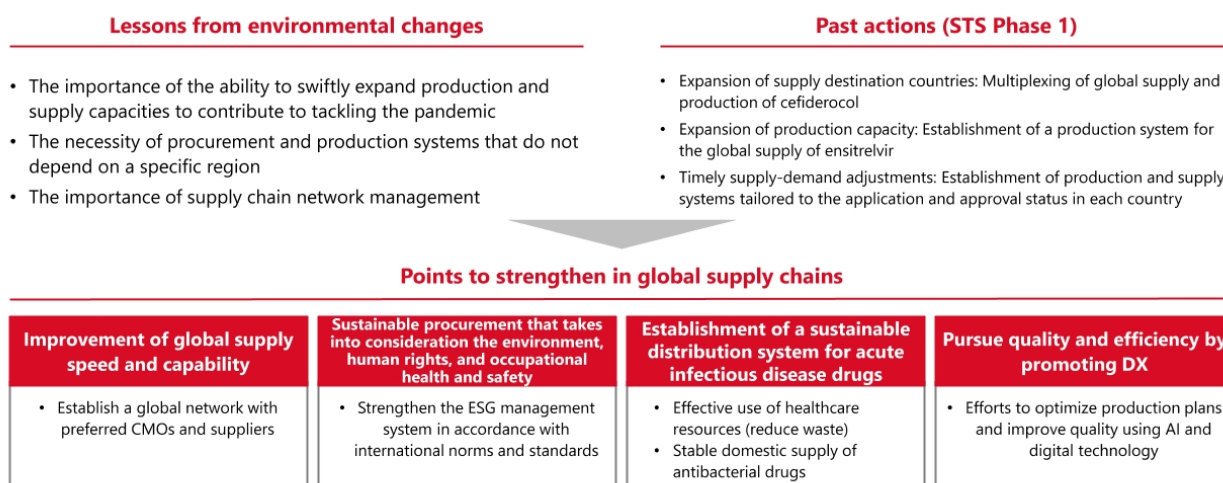
We would like to extend that as a business model, and come up with a system that would allow us to raise sales without having such a large sales infrastructure. In Asia, how do we expand first to China and then to ASEAN? If we go by the current framework, we are thinking mainly of Ping An Shionogi C.

We would like to proceed in this area as a realistic discussion, and at present, I think it is not so difficult to increase sales without spending so much on infrastructure and other costs. Of course, we will be making local efforts, for example, with ensitrelvir in China, where we have partnered with Chia Tai Tianqing Pharmaceutical Group and Shanghai Pharmaceuticals. I believe that we can manage to establish a top line as an extension of these efforts.

Strengthen the management base and Contribute to a sustainable society: ④Key Strategic Priorities

## Building a Foundation for Realizing

### Improve the resilience of increasingly important supply chain management to strengthen global supply capabilities



Dr. Hanasaki has a global supply chain. I think it is correct to say that COVID-19 has caused a lot of pain here. We experienced how fragile the supply chain is. The global supply chain is a very high priority for us, and this is a focus for us.

Especially in the midst of geopolitical risks, how much of the work will be done in Japan and how much will be done while taking advantage of the global supply chain? It is not an easy decision to make, especially we work in the infectious disease area. We are currently putting a lot of work into this.

On the other hand, the second issue from the left, which is how to deliver acute infectious diseases to governments or LMIC, is also a very difficult one.

On the right side, we have Shionogi Pharma as a 100% group company. Originally, continuous production and precision in production planning were the main themes there. We still believe that our strength lies in our ability to consistently produce high quality products with fewer people, and we will continue to work in this area.

## Investment and Financial Strategies



I have mentioned this several times, but regarding our investment strategy, first of all, we consider JPY300 billion for research and development over three years as one of our own standards. Of course, we do not intend to spend JPY300 billion when there is nothing to develop, but at the moment, even this may not be enough. However, as I mentioned earlier, our base is to promote the development of products that we are confident in based on unmet need.

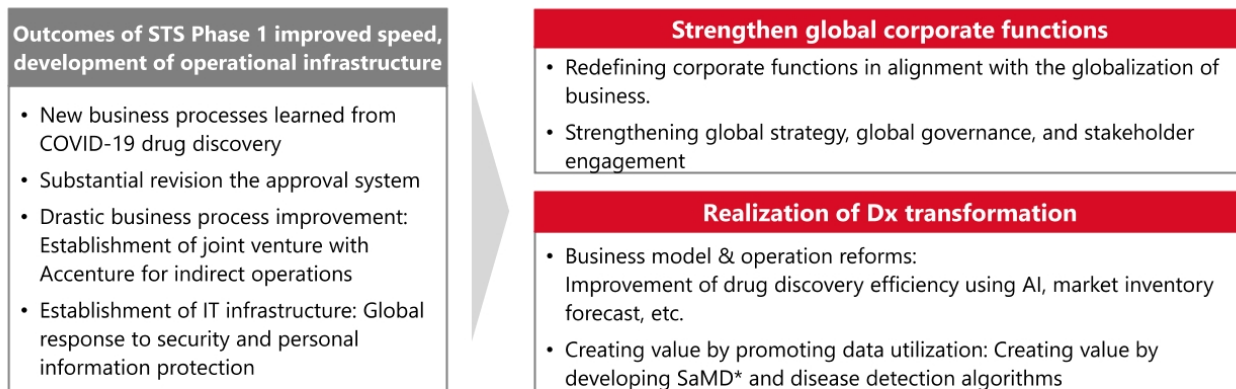
Regarding business development and business investment, I am sure that our investors and others can trust us, but we have not and will not make reckless investments. However, we would still like to proceed with the necessary technology and pipeline development, although we would have to invest at this point in time, if it is at a good price.

It is probably not that much of a surprise that we include it here as a financial KPI. If you consider a DOE of 4%, EPS of JPY600 or more, and ROE of 14% or more as a single concept, we have increased dividends for 11 terms so far. We plan to increase dividends for 14 consecutive terms and for the next three years as well.

In that sense, the schedule for the 12th term is set. We are considering this figure based on our basic policy of increasing dividends for 14 consecutive fiscal years, while at the same time considering share buybacks and other measures in a flexible manner and on a certain scale.

## Action to Increase Global Competitiveness

### Achieve operational transformation/value creation globally, leveraging our experience from COVID-19 drug discovery



We have a few more pages to go. Let's press on.

The second point from the top on the left is that we have already abolished our approval system, which is probably quite rare. What this means is that the jurisdiction, for example, if it were Dr. Keller's department, we cut out some of the formality surrounding decisions in R&D, so that we can make progress speedily.

For example, Even if the investment is JPY100 million, if the investment is a very heavy for the company, bring it to the board meeting. Even if it is an investment of JPY 2 billion, it doesn't matter who makes the same decision. Of course, as an internal mechanism, everything is recorded and can be reviewed, but if it's JPY 100 million, it's not a request for approval, or if it's 99 million yen, it's not a request for approval. I'm trying to stop it, and proceed with it properly based on substance.

For example, if Dr. Keller decides on his own that he has decided to spend another JPY2 billion, he would report to the management committee. Why did we decide to do this? We have already made a decision, so we are moving forward, but we discuss why we made the decision we did, and if we find ourselves saying, "That's a little too much, don't you think?" then we say, "next time, we'll change it." Since all records of why a decision was made are kept on the computer, including who was present at which meeting and what the discussion was about, there is no need for a request for approval, and we are trying to speed up the process.

This is one example, but there are other examples, such as the previously announced BPO outing with Accenture, which will be implemented with speed, transparency, and traceability. I am proud to say that our company has changed considerably since last July. I believe that everyone is now making decisions independently and voluntarily deciding what to proceed with. I would like to continue this trend and further increase the speed of the process.

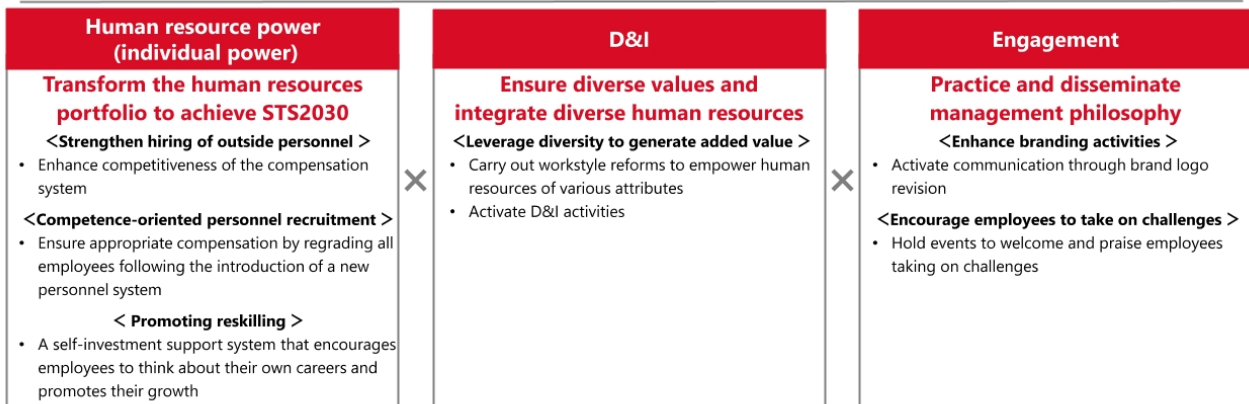


Strengthen the management base and Contribute to a sustainable society: ⑥Strengthening management and ESG  
**Strengthen Human Capital to Achieve the 2030 Vision**

**Acquire new Capabilities/Promote in-house integration and execute growth scenarios**

Build on our existing strengths (business execution capabilities, expertise) to acquire and develop new strengths  
 Evaluate the progress of initiatives using KPIs and strengthen dialogue with stakeholders (Major KPIs: short-term – succession plan execution status, self-investment support utilization rate, etc., medium- to long-term – progress in talent management, etc.)

**Points to strengthen regarding human capital**



Human capital management is the area where we have spent the most time, in a sense, in both management and Board meeting discussions. Naturally, when I think about the next three years, or the next seven years, I am thinking about how to create talent, see talent, and then give it a chance to go to the next stage.

Next, human resources, DE&I, engagement. Some people say that this is a matter of multiplication, some say it is addition, and some say it is all independent, but unless all of these are realized, the Company will not be able to go ahead with a management approach based on human capital. We have spent considerable time discussing this issue and will continue to do so in the future.

Strengthen the management base and Contribute to a sustainable society: @Strengthening management and ESG

## Addressing material issues impacting customers and society

Aiming to achieve both growth as a company and contribution to a sustainable society by strengthening our response to material sustainability issues through dialogue with stakeholders

**Environment**

**Implement the 2030 CO2 reduction plan to become carbon neutral**

**[Medium-term target]**  
 Scope1-2 : FY2030 : 46.2% reduction (compared to FY2019)  
 Scope3 : FY2030 : Category 1 20% reduction (compared to FY2019)

**Society**

**Reinforcement of Consideration for Human Rights in Our Company and Partners**

**[Medium-term target]**

- Continuous implementation of human rights due diligence
- Risk assessment of important partners, on-site audits

**External evaluation results**

- Became the first pharmaceutical company to be certified as an "Eco-First Company" 
- FTSE : 3.6, MSCI : AA, DJSI : 63
- CDP Climate, Water Security: Double A List 

We have made a clear commitment in terms of sustainability, and I believe that we are really making steady progress forward in this regard.

I would like to take this opportunity to assure you that we will continue to make progress in the areas of environmental, social, and external evaluation, as these are areas in which we cannot go backwards.

## Summary: Overview of STS Phase 2 ('23 -'25)

**Build on the results of Phase 1 to achieve global growth**

- Leverage business capability that was improved in all aspects during the COVID-19 pandemic
- Achieve significant global growth over three years, centered around ensitrelvir

**A paradigm shift of the HIV franchise**

- The market environment changed drastically, including the growth of long-acting formulations
- Progress R&D for even more significant growth in the medium to long term

**Acquire growth drivers**

- Enhance the pipeline through aggressive investment leveraging a robust financial base
- Concentrate investment in high-need, high value pipeline assets; shift resources flexibly, with approaches cultivated through COVID drug discovery

**Strengthen the management base**

- Transform human resources and the organization
- Promote ESG management: Achieve growth in harmony with society

Last but not least.

In summary, the theme of this issue, as I said before, is that the situation has changed considerably regarding HIV. I believe that the three years of pandemic experience we have had gave us a clearer picture of what we need to do. We have been in the vaccine business for the past three years, and although we are not selling them yet, we are getting very close. That is the kind of change we need to make. In addition, there is the power of our own international expansion, which has managed to bring cefiderocol to sales of over JPY10 billion.

In these and other areas, we want to go to the next phase. This revision to STS2030 is a summary of our commitment to strengthen our management base, including non-financial and financial indicators.

Lastly, you may say that since this is a revision, we could have just gotten on with it internally. However, I would not say that the revision is a new medium-term plan, but I would like to take this opportunity to say that many things have changed in terms of content.

We will continue to receive your questions and comments, and we hope to achieve the figures we have presented this time, as well as the qualitative and quantitative KPIs, in 2023, 2024, and 2025. Thank you for your attention.

## Question & Answer

---

**Kyokawa** : We will now take your questions.

Mr. Hashiguchi from Daiwa Securities.

**Hashiguchi** : Hashiguchi, Daiwa Securities. Thank you.

I would like to ask about the expected HIV sales approaching 2040. I would like to know what the future prospects are in terms of sales and prices.

There may be a possibility that pressure to lower prices will increase in the future for items such as IRAs. People tend to think that manufacturers have already recovered their R&D investment for these to some extent. I would be interested to hear how those effects are reflected in the outlook you provided today.

**Keller** : Thank you for your question. One important thing to note is that the long-acting form makes a big difference for patients. A patient who is taking oral medication every day will go to medical institution once every one or two months. In future that could go to once every three months or even six months. For our part, we want these long-acting types to penetrate the market as much as possible. We would like to do this before the patent expires on the oral drug.

It would be very difficult for a patient to go from once-a-day oral to once-every-three-months or once-every-six-months format, and then ask to come back to once-a-day. There are privacy risks, for example.

If there is pressure by payers, or governments, to lower prices, it will negate the value of those long-acting types. That would be very difficult to do. So it is different from general price pressure.

Of course, in the US, there is always pressure from the government's point of view. Of course, there is general pressure on the price of pharmaceuticals.

But when it comes to HIV, this is true in the US as well, especially in places like this, I don't think that this is a case of saying switch because a generic is available, as you mentioned, and then go back to the previous drug.

**Hashiguchi** : Thank you. There is one more point.

I would like to know your thoughts on the sales outlook for COVID-19 treatments. On page 11, I think you have written a forecast, mainly on a volume basis, of how many of those diagnosed will be using this drug.

Page 9 describes the scale of sales, and it almost looks like the size of that box is not much different on page nine than on page 11.

In terms of your company's perspective, what is your estimate of the number of people who will be affected by the disease and the number of people who will be diagnosed with the disease? How do you estimate the sales as shown on page nine, depending on how the unit price changes or does not change? What are your projections for sales as shown on page nine?

**Iwasaki** : Let me first talk about the outlook for Japan.

The current treatment rate is roughly 16%. When Xocova was first distributed to the general public, it accounted for less than 10% of the total, so although there has been some growth since April, I believe it is still low.

In fact, I would like to see them go to 20% or 30%, at least, this year, or this season, under the current circumstances. Ultimately, as we always say, the treatment rate for influenza is 90%. If we can achieve the same level of early diagnosis and treatment as for influenza, the number of patients will depend on the epidemic, but we will naturally be able to achieve the target figures we are currently showing.

One more thing, regarding NHI prices, we now have public funding. The government has stopped the project in terms of the budget for September and beyond, but we still do not know what will happen in the future in terms of outbreaks and the needs of society. We would appreciate your understanding that what will happen to this NHI price is still under consideration at this time.

**Hanasaki** : Overseas, in terms of volume, for example, Paxlovid in the US has been growing considerably. Our products have added value to this product. I think one of the key points is to shift the market by adding value in the areas of these two global trials, prevention and long COVID.

Meanwhile, China and Europe each have their own unique characteristics, which we will develop for accordingly. We then aim to expand in the future. Prices vary from country to country, and in the case of the US, the price is based on the Paxlovid price.

As for Europe, I think it is necessary to negotiate depending on each country's reimbursement system and financial conditions. Especially for China, we cannot set the price so high if we include the fact that after the NRD, various drugs are also available in the country. We set prices to some extent according to the situation in each country, and this will be reflected in our forecast.

**Hashiguchi** : So then the scale of the graph on page 11 is a little different from what your company is assuming with the sales on page nine.

**Teshirogi** : Yes, that is correct. The price is also difficult to predict, since we cannot handle on our own. For overseas, we have a model that includes competing products, and we give a rough estimate of the number of products at about this price.

Pfizer has already given us a picture of Paxlovid, which is already being drawn all the way to about 2026. I wonder if they are probably making such calculations and then slightly lowering the unit price and slightly raising the number.

**Hashiguchi** : Thank you.

**Haruta** : My name is Haruta from Credit Suisse.

I believe that the JPY500 billion in the last medium-term plan for business investment was not achieved this fiscal year due in part to the pandemic. The current medium-term plan actually calls for JPY300 billion over three years of R&D. What scale do you envision for this update?

There has been an upward revision of sales for FY2030, and I was wondering if there is a possibility of increasing this from the forecast JPY500 billion. If so, in which areas, and how do you draw the line between investment and M&A? I would like to know more about this.

**Keller** : As for investment, it's R&D. I think there will be some acquisitions from the outside. As for the market at the moment, it's a pretty solid market, especially with regard to outside acquisitions. Suffice it to say, we have been doing a lot of reviews over the past year and a half, conducting very firm due diligence. We are also talking a lot with that target in mind.

Of course it costs a certain amount of money, and it is very competitive, but while keeping a firm focus on quality, we are hopeful. Even though the current focus is very difficult to market, many places are moving.

Also, if you look at unmet medical need, which is actually an area we are concentrating on, there are some areas that are not necessarily the core focus of megapharma.

**Haruta** : Thank you very much. JPY300 billion in three years, what do you think about that figure?

**Teshirogi** : To be honest, given our current financial capacity, I don't think the banks and others would be so opposed. I think we can probably buy up to JPY2 trillion or JPY3 trillion if we want to.

So I don't think there is any hesitancy there if it is really necessary for us for the future. However, as Keller said, when we think about products and companies, I think the current level is probably around JPY200 billion, JPY300 billion, or 400 billion. This is the initial screening level, so we should start from that area.

Actually, as for money, there is not much of a limit. If anything, the primary consideration for the Company's growth is what I believe must happen during this seven-year period.

**Wada** : My name is Wada from SMBC Nikko Securities. Thank you.

I would like to ask you about the introduction and out-licensing of the pipeline.

One point I would like to ask is how you have revised the target of 60% for in-house development. We would like to ask you if you have taken into account the sales target of JPY800 billion for FY2030, which includes the products you have introduced and will introduce in the future.

Also, in terms of out-licensing, I think the early-phase pipeline is quite a diverse product line, such as anti-obesity drugs and oncology. I would like to know how you think about derivation from the viewpoint of lead-out.

**Keller** : I think there is a great opportunity with regard to implementation. It will be a major component in FY2030 sales as well, however regarding the current target, we do not include future in-licensed revenue.

One of our goal is to create a network of collaboration, and do various phases, various research and development areas. Therefore, in the future, it will be difficult to draw a line that says 100% in-house

development in this area or 100% zero in this area. However, in-house compounds are Shionogi's strength, and we will continue to focus on those as well.

However, we would also like to take advantage of outside expertise in a flexible new way. We would like to take various forms, not just M&A, not just introductions, but various ways, such as collaboration with venture companies.

Then there is partnering for out-licensing. For our part, we would like to increase our global strength. So, for example, oncology is very complex, requiring combinations of various drugs and large-scale clinical trials.

Therefore, I believe that partnering instead of out-licensing makes sense. From that perspective, various ways of doing things make sense.

**Kyokawa** : We will now take questions from the media. Any member of the media in the audience with questions, please raise your hand. You.

**Reporter A** : Thank you.

Some of these questions are quite similar to the previous ones. I think coronavirus is attracting a lot of attention. Looking at the graph on page 11, FY2030 shows that ensitrelvir is the COVID-19 treatment, and I think this includes the purchase of the treatment, but again, you are saying that you expect this infection to continue to have a certain prevalence. In this context, may I ask again about your vision for the future of Xocova and therapeutic drugs in terms of how you plan to increase sales?

**Teshirogi** : Yes, as I said before, I think it is really hard to see We think the situation is quite unfavorable, including flu. We are looking at the situation five or ten years from now.

We need to make sure that we have adequate coverage for both flu and COVID. The details of human infection via avian influenza, which is said to have occurred in India, Russia, and China, are not yet clear.

However, the new strains of influenza that we are dealing with internationally are still quite toxic. Furthermore, there have been a few recent examples of movement from avian to mammalian species. If the virus is passed to people, as I mentioned earlier, the change in surface antigens is inherently faster and greater with influenza, so I think it is not good to have people all over the world infected like COVID-19, causing various mutations to appear in various places.

Our policy, or perhaps I am not so wrong, is that if the virus is not removed from the body through early detection and treatment, then this will not readily come to an end.

Of course, vaccines are important, but even the best vaccines cannot stop 100% of infections, nor can they stop the onset of disease. It might be exaggerated that we need to reduce the global virus burden, but we strongly believe that we need to do that by using vaccines and treatments effectively

In a situation where infections have not stopped, we may see the emergence of COVID-19, SARS-CoV-2, and possibly SARS-CoV-1 once more, as well as influenza, not only H1 and H3, but H5 and H7 as well.

We need to discuss stockpiling with the governments of other countries. I believe that the need for medicines for acute respiratory infections, as shown in the schematic chart here, will not go down.

Our corporate planning department is also simulating various patterns in terms of unit cost and patient volume. In any case, it is not so easy to reduce the number of cases. We believe that the most important thing is to eliminate the virus as soon as possible when it is contracted, especially in light of long COVID. I think that

by promoting this concept, including the data, it would not be so strange to see examples such as the ones in the schematic chart.

**Kyokawa** : Any other questions? Over here.

**Reporter B** : Let me ask you something.

In STS2030, which was published two years ago, the KPI for the ratio of overseas sales target was not achieved in FY2022. The figures are not easy to see because of the large effect of Xocova. Is that why the KPI itself has been revised? Also, can you give us a big breakdown of what is in here?

**Teshirogi** : The contents are divided into four categories: US, Europe, China, and others. Although the figures are quite detailed, I'm afraid I cannot give a breakdown today.

From a macro perspective, given how the pharmaceutical market in our country is going to shift around new drugs, it is honestly difficult to think that it is going to get bigger and bigger.

Of course, we in the pharmaceutical industry, including the Pharmaceutical Manufacturers Association of Japan, the Federation of Pharmaceutical Manufacturers' Associations of Japan and PhRMA, need to expand the market with appropriate evaluation of innovation, or else we will face drug lag and drug loss.

Realistically, I wonder if it would be possible to grow that big within a few years. I think it is an appropriate strategy for us to expand overseas, which is currently a low percentage for us.

At the moment, the main focus is on ensitrelvir, but cefiderocol has been successful, and in Europe, Rizmoic are actually growing very well. Setting overseas growth as a percentage KPI is not only for ourselves, but also for our company. It has a great effect of announcing that Shionogi as a whole will not grow if we do not expand overseas.

In that sense, it is important to make a clear announcement that if we cannot grow this much overseas, we have no future. Of course, the figures are backed up, but this time we dared to include it as an important KPI.

**Reporter B** : Thank you. In relation to this, on page 12, in the vaccine business page, I think you have mentioned SHIONOGI would like to make vaccine business 100billion business, mainly overseas, in the Infectious Disease Vaccine section. In Japan, I think you are still in the process of applying for coronavirus marketing approval, but please tell us again how you intend to achieve the goal of 100 billion business, including development for flu vaccine.

**Teshirogi** : Yes, vaccines are also a business of volume multiplied by unit price. We are doing our own simulations to determine how much to produce at what unit price.

For example, when we were originally working with HanaVax on intranasal vaccines, we always imagined something like the pneumococcal vaccine. Then, as for the universal vaccine, we, at the institute, are now working on a universal vaccine that will cover at least that year's mutations with one shot. This applies even with the COVID-19 strains that we have now, where we are seeing repeated mutations.

The main countries that have the most sales are Japan, the US, and Europe, but we are also looking at how many and what kind of unit price we can charge. We have included three or four types of vaccines in this figure, along with a development plan for vaccines that are slightly different in concept from those currently on the market.

**Kyokawa** : Next question.

**Reporter C** : Thank you.

I would like to ask you about human resources. You said in the presentation that Ms. Sawada mentioned internally that the globalization of SHIONOGI headquarters is needed. I thought she was expecting to see a lineup of foreign nationals on the Board of Directors. As you said in the presentation part, Ms. Sawada mentioned internally that the globalization of SHIONOGI headquarters is needed, and I thought she was expecting to see a lineup of foreign nationals on the Board of Directors like Takeda. To what extent do you think globalization is necessary for SHIONOGI headquarters?

**Teshirogi** : That is not the point Sawada is making about a global headquarters.

For example, to put it in symbolic terms of what kind of personnel system we are going to create philosophically, at the moment, it is no longer possible for HR for the entire of Shionogi to be run from the head office in Osaka, Japan. That's what we've done to date.

So, for example, even if we have people from overseas, or people outside the pharmaceutical industry, come to Shionogi to progress DX, we do not originally have such a personnel system that includes what the world would call a job-type system, nor do we have a pay system.

We have a personnel system that allows people in their 20s to become managers, but we have only just introduced this system, so it is not yet at the level of a global personnel system that allows people in their 20s to come here and do their own work like Dr. Keller did, including people in the United States and Europe.

Whether it is general affairs or legal affairs, everyone is at the level of what they have done up to now, and how to do it globally from here. Mr. Sawada thinks we should do this. I am not sure if they can think of such things overseas or globally, and I wonder if the people who think about it are only those who have been at Shionogi for a long time, and if they can even think about the system.

Therefore, we believe that the diversification of research, development, and production will not start unless the people who think about and operate the systems are more diversified. We are discussing this.

**Reporter C** : Okay. One more point, your company have made this kind of roadmap in the revision of the medium-term plan. Dr. Teshirogi has been President since 2008, which is a very long time, how far do you think there is your responsibility as a President?

**Teshirogi** : Yes, of course, we have a Board of Directors, and we have both a Nominating Committee and a Compensation Committee. The biggest theme in the nominating committee is probably always, in any company, if you grab a first-year president, for example, what is the succession plan, I think your question is also probably same thing, so we have a lot of discussion about that.

For our part, although age is not everything, it is important to have a certain level of young people with management experience and global experience. Since it is not possible to go all the way to the top and immediately move up with only one experience, we consider succession within a pool of several people. That is the idea of our nominating committee.

The current thinking is that we should try to bring them experienced the position of Supervisory Unit within their 40s or early 50s as soon as possible, not just after they have done one job, but after they have done two or three jobs. I think that's the way of thinking now.

That's not what I meant when I said I was going to do it for such a long time. Based on this, the nominating committee meets with new executive officers and directors who are one step ahead of our executive officers every year, and we would like to establish a system that allows for as much diversity as possible.



**Reporter C** : At the moment, I think that is the point of a succeser in the future, but as for Dr. Teshirogi, how far do you want to go?

**Teshirogi** : I was thinking about stepping down before thinking that the HIV cliff of FY2027 or FY2028 was going to be really huge. However, when we realized that, I thought that it would be irresponsible to leave someone else with that problem. I thought it would be best to set a course first.

I think that we have established a certain base, including the transformation of the HIV franchise, with ViiV's sales and 598 from us. If we can see the roadmap of how much we can expand our franchise, we will not disappear tomorrow. I believe that I am fulfilling my obligations.

**Teshirogi** : At this point, Xofluza, cap-dependent endonuclease Inhibitor, is effective with regard to the highly virulent avian influenza that we have tested against. We are confident about this.

Production takes 14 months, so as you say, if we were asked to supply some now, it would be impossible. Normally, we would talk with the government of each country, but talks with the government are not going smoothly, because we also have to talk with Roche which has out-licensed the rights to overseas development and sales.

However, I am not saying this one by one, but Xocova's facilities and Xofluza's facilities are shared, at least in terms of formulation, so on the contrary, Xocova was able to be made quickly. If we were building the factory, we couldn't make it, but we converted it.

Because of that, we are dropping the output of Xofluza. We are just now starting to talk with Roche about which one and how much to make. Frankly speaking, even if we make this now, it will be available next summer, so I think we need to speed up the process a bit.

On that topic, a few words about page 11, which you asked about earlier. Here, in oral therapeutic drugs, which is basically COVID-19, we actually have in our minds that in some cases, a part of this may be used for influenza. We have included this in the "this is how much we need to go for infectious diseases," but we have not included any pull-type discussions about stockpiling or how much each country's government will purchase. I think you are right in pointing that out.

**Kohtani** : Okay. Finally, I would like to talk about vaccines.

Certainly your company has a pretty good track record when it comes to vaccines. In fact, if all goes well, I think it will be approved this year. That said, I was quite puzzled by some of the expansion culture and manufacturing. Since the diversion of vaccines and mRNA vaccines for influenza and other such diseases is now being discussed, the threat of mRNA has probably increased considerably from the plan made in FY2020. In the midst of all these troubles, can you tell us one more time about the background behind your increased confidence in this vaccine business? Thank you.

**Teshirogi** : Among the technologies we have now, the progress in universal and nasal vaccines I mentioned earlier have been very significant, so I would like to commend Keller and the rest of our research team for this. Sorry to be so forward but I would like to praise them. The results have been really interesting, and I think we have a good chance of making a sale, including possibilities to commercialize these results.

We have a very extensive supply chain network under Hanasaki. We don't have to make everything ourselves. We are already talking with at least a few companies that can help us. Now that our network has expanded considerably, we have been talking with these people consistently, and we have reached the point where we can manage to have two, three, or even four types of products.

This is not to say that M&As do not include those who are involved in vaccines, especially on a global basis. We would like to promote vaccines as an area to be strengthened.

**Kohtani** : Okay. Thank you very much.

**Kyokawa** : Thank you very much. Next, Mr. Ueda from Goldman Sachs Securities. Please go ahead.

**Ueda** : Ueda, Goldman Sachs Securities.

I would first like to ask you about the changes since the last medium-term plan. Looking at the revised figures, originally, sales of JPY500 billion in FY2024 went to sales of JPY550 billion in FY2025, and sales went from JPY600 billion to JPY800 billion in FY2030. These are due to the contribution of COVID-19 treatments as shown on page nine, as well as to the increase in the royalty income projection. I think that the contribution of COVID-19 and the increase in the royalty income forecast are also taken into consideration, and that there may be some decrease in the other areas.

I would like to know if there are any points other than the main points you have explained this time where your viewpoint has changed.

**Teshirogi** : Individually, they are not large differences. For example, three years ago, sorry to be a bit detailed, but S-600918, for example, was in there. Now that we are shifting our focus to doing S-309309, S-531011, and S-005151, a change in the product mix is occurring.

For example, we are considering a much higher number for S309309 than we did three years ago, as well as for S-005151 and S-531011. When you put it that way, it doesn't look as if that was the case.

We draw a fairly precise line for each product and add it, and then, of course, reduce it by a percentage before making this announcement. I think we drew a reasonable line, given the change in product mix and our current sales projections of it.

**Ueda** : Yes, sir. Thank you very much. I was wondering if the increase of JPY200 billion, for example, could be attributed to the increase from coronavirus and the increase in royalty payments. I was wondering if you could tell me what the positive figure for each of those would be.

**Teshirogi** : Yes, it is not the same as the internal figure.

**Ueda** : Yes, I understand. Thank you very much.

Secondly, I would like to talk about the concept of global strategy. While I heard that you have gained a little more confidence than before in Europe and the US, I don't think there were many comments about the China business this time around.

Can you tell us about the change in positioning in this area, and in the area of business development? Should we not think too much about acquisitions in order to strengthen sales?

**Teshirogi** : Yes, regarding China, Keller, myself and the most senior person at Ping An China discussed the situation before this meeting. The commitment is very strong. From our point of view, there is almost no blip in the numbers that we have in mind for FY2025 or FY2027 years. Sorry, I didn't happen to mention it this time.

However, I think it is very important for everyone, including Hanasaki, to get approval for ensitrelvir as soon as possible, and to work with Chia Tai Tianqing Pharmaceutical Group and Shanghai Pharmaceutical to properly show how much we can sell here. In the sense of "don't talk big when you don't have the results," I

would like to show that we have achieved the results and sold this amount of product, and then show what kind of products we will develop and sell in China next.

The JV with Ping An is a driver for our future growth in China. Ping An's top management has said that they are willing to invest all their resources in the JV in order to expand the business.

Infectious diseases such as these are not easily predictable, partly because of the politics of government licensing. We think it will be soon, but we thought we would wait until we had the numbers to include, so if it sounded like there was a problem, I apologize for that.

In the sales area, in principle, we do not intend to do M&A just to increase sales. If a company happens to have an interesting compound and we want to work with them, but they also sell other items and are engaged in other sales, it may be difficult to ask them to separate the other items from the compound of interest. In such a case, we would consider buying a company in its entirety. This would not be done to buy sales, but when there is a development or late-stage compound that we want.

**Ueda** : Understood. Thank you very much. That is all from me.

**Kyokawa** : Next question. Ms. Kumagai of Mitsubishi UFJ Morgan Stanley Securities, please go ahead.

**Kumagai** : Kumagai. Thank you.

There is some overlap with Mr. Ueda's earlier question. On slide 12, you have introduced the programs that are scheduled to be launched in FY2026 and after, but I think that no information about a PoC is available for many of them. What do you consider the probability of success, and how do you incorporate this into your plans for FY2030?

In order to achieve the FY2030 KPIs, do you need to succeed in all of the items listed here, plus a certain scale of business investment, or is it okay if you fall short in some of them? Are we talking about increased business investment if some fail? Thank you.

**Teshirogi** : Realistically I would like to say that I want to succeed in all of them, but it is unlikely. However, in the case of viral infections, for example, if the quality is this good in Phase I, we can expect the same level of success in Phase II and 3, and we can adjust the yield based on our accumulated strength. We do make adjustments based on the strength we have accumulated so far. Regarding these 6 items to be launched in FY2026 and beyond, I don't think that all of them will go all the way.

However, even if some of these are no good, we have the next pipeline item, and as you just mentioned, we are considering the possibility of compensating for this through M&A and other means.

**Kumagai** : Understood. Thank you very much.

**Kyokawa** : Next, I would like to continue with questions from the media. Please go ahead.

**Reporter D** : Thank you. I would like to ask about your policy on the priority areas of research and development, such as infectious diseases, oncology, and neuropsychiatry, among other new product candidates.

**Teshirogi** : Yes, I think that what we have now remains what we consider to be very competitive. As Dr. Keller answered earlier in response to your question, for example, with 011, the solid cancer treatment, do we intend to do the entire process from start to finish? That would cost a lot of money, and we would have to consider a lot of concomitant therapies, among other issues. We are considering the possibility of working with a partner in this regard.

For example, in the case of obesity, we will discuss the weight reduction and safety of 309 itself, but in terms of the market, if we are asked what would happen if it were combined with GLP1, for example, we may have to consider the possibility of combining it with a partner who has GLP1. In this respect, we are selecting compounds that are truly competitive based on unmet need. Other than that, quite a few were dropped at R&D Supervisory Unit.

We are now dropping all of the "interesting but not competitive" items, so we believe that the remaining items are still quite competitive at this point in time.

Some may say that Shionogi has never done sleep research on its own, but we believe that we have a certain amount of knowledge about sleep in our CNS background, and if we are going to do it anyway, we will do it only when we have identified a sleep-related field that is very competitive worldwide.

As I mentioned earlier, the pediatric part is a little different. In some cases, however, the development of children's drugs may not be so profit-centered. There is also the issue of supporting a society with low population growth. We think it is very important to make available treatments for children. For the rest, we will select globally competitive products and concentrate investment in them.

**Reporter D** : Thank you.

**Kyokawa** : Yes, we have a few minutes left, and I would like to take the last question. Please go ahead.

**Reporter E** : Thank you. I would like to ask Dr. Teshirogi one question.

I think the purpose of today's discussion was that you are on track to overcome the FY2027 or FY2028 HIV cliff, but there are still some challenges to be addressed, such as infectious disease countermeasures, globalization, and strengthening of management.

Of these, if there are any pressing challenges that Dr. Teshirogi needs to focus on, or any challenges that you would like to do something about first, which would it be?

**Teshirogi** : This is priority number one, to what extent we can increase our ability to increase overseas sales on our own. I think we have a reasonable pipeline, but up until now, we have been seeking help from outside sources to a certain extent, as I mentioned earlier with Roche. I wonder to what extent we can build up sales centered on our own efforts and bring them closer to the JPY800 billion in FY2030 that I mentioned earlier.

I know you are all wondering if we can achieve sales of JPY800 billion, but we are thinking of an internal plan that is a bit above this. I think it would be good if we could just do what we think is best, but for example, with the Chinese ensitrelvir issue I mentioned earlier, we have to show results.

As I mentioned earlier, globalization of the head office is actually one of the most important factors for increasing global sales, such as a global personnel system and how to secure and promote global human resources.

**Reporter E** : Thank you very much.

**Kyokawa** : Yes, thank you. This concludes the briefing on the revision to the "Shionogi Transformation Strategy 2030", our medium-term management plan. Thank you all very much for taking time out of your busy schedules to join us today.

**Teshirogi** : Thank you very much.

[END]