SHIONOGI & CO., LTD.

3rd Quarter of Fiscal 2025 Financial Results Conference Call

January 30, 2026

Presentation

Kyokawa: Thank you very much for your participation today despite your busy schedule. My name is Kyokawa, Vice President, Corporate Communications Department, SHIONOGI & CO. We would now like to begin the presentation of SHIONOGI & CO., LTD.'s financial results for the 3Q of fiscal year 2025.

Today's conference call is being held at our Tokyo Nihonbashi office, the Torii Nihonbashi Building. First, let me introduce today's speakers. Isao Teshirogi, Chief Executive Officer.

Teshirogi: I'm Teshirogi. Thank you .

Kyokawa: Next, John Keller, Director of the Board, Senior Vice President, R&D Supervisory Unit.

Keller: I'm Keller. Thank you .

Kyokawa: Lastly, Masako Kudo, Corporate Officer, Senior Vice President, Corporate Strategy Division.

Kudo: I'm Kudo. Thank you .

Kyokawa: Now, let me give you a brief explanation of today's process.

First, Teshirogi will give an overview of the financial results for Q3 of FY2025, and then Mr. Keller and Mr. Teshirogi will present the second half, covering Toward the Realization of the 2030 Vision. We will then have a question-and-answer session.

Let me begin at once. CEO Teshirogi, please go ahead.

Highlights of the Third Quarter

- **Revenue, operating profit, and profit attributable to owners of the parent for the cumulative third quarter reached record highs**
  - As a one-off factor boosting profit, a gain on negative goodwill gain associated with the acquisition of JT Group's pharmaceutical business was recorded*1
- **Revenue for the quarter amounted to 147.7 billion yen**
  - TORII's sales are beginning to be fully reflected in financial performance
- **Advancing business investments to accelerate medium- to long-term growth**
  - Conversion into an equity-method affiliate through additional investment in ViiV Healthcare*2
  - Acquisition of the edaravone business from Tanabe Pharma*3
  - Completion of succession of JT's pharmaceutical business and acquisition of shares in Akros Co., Ltd.*4

*1 Provisional accounting prior to the completion of Purchase Price Allocation
*2 January 2026 Press release *3 December 2025 Press release *4 December 2025 Press release

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Teshirogi: Thank you very much. I usually do not attend conference calls in Q1 and Q3, but since there were some very significant developments in Q3, I am here today to answer any questions you may have. Thank you .

Let me move on to page 4. As for the highlights of this fiscal year, the Company achieved record highs in revenue, operating profit, and profit attributable to owners of the parent for the cumulative Q3.

I will explain this in more detail later, and as a one-off factor boosting profit, there was a gain on negative goodwill associated with the acquisition of the JT Group's pharmaceutical business. Excluding this, operating profit and EBITDA were flat and almost the same as the previous year.

Quarterly revenue of JPY14.77 billion, excluding the Q3 FY2022 quarterly results that included the Japanese government's purchase of Xocova, record-high quarterly sales. We are beginning to see the path toward the JPY150 billion target. We are gaining confidence in our ability to achieve this goal.

As I mentioned earlier, although the originally announced schedule was for Q4, regarding ViiV's additional investment, we completed nearly all deals during Q3. This included the transition to an equity-method affiliate, the acquisition of the edaravone business from Tanabe Pharma, and, as planned, the full integration of JT's pharmaceutical business into our group as of December 1. Consequently, Q3 was an exceptionally busy period.

Financial Results

**Revenue and all profit items increased year-on-year,
showing steady progress toward achieving the full-year forecast**

(Unit: B yen)

	FY2025			FY2024	Y on Y	
	Forecasts Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	500.0	**360.7**	**72.1**	333.6	**8.1**	**27.1**
Operating profit	185.0	**148.7**	**80.4**	129.2	**15.1**	**19.5**
Profit before tax	232.0	**191.3**	**82.4**	155.9	**22.7**	**35.4**
Profit attributable to owners of parent	188.0	**158.2**	**84.2**	133.8	**18.3**	**24.4**
EBITDA*1	206.0	**147.8**	**71.7**	146.4	**1.0**	**1.4**

*1 Earnings Before Interest, Taxes, Depreciation, and Amortization: Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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Financial results.

Revenue was JPY 360.7 billion, up 8.1% year-on-year; operating profit was JPY 148.7 billion, up 15.1%; profit before tax was JPY 191.3 billion, up 22.7%; profit attributable to owners of the parent was JPY 158.2 billion, up 18.3%; and the progress rate of sales was 72.1%, which seems a little low. As I mentioned earlier, on a quarterly basis, we have achieved an increase of just under JPY 150 billion, so looking at the full-year forecast, the figure of 72% may seem low against JPY 500 billion, but at the current pace, if Q4 goes smoothly, I believe we are on track to achieve our full-year guidance.

Statement of Profit or Loss

(Unit：B yen)

	FY2025 Forecasts Full year	FY2025 Apr.-Dec. Results	FY2025 Achievement (%)	FY2024 Apr.-Dec. Results	Y on Y Change (%)	Y on Y Change
Revenue	500.0	**360.7**	**72.1**	333.6	**8.1**	**27.1**
Cost of Sales	16.4 82.0	**15.1** **54.3**	**66.3**	13.8 46.0	**18.1**	**8.3**
Gross profit	418.0	**306.3**	**73.3**	287.6	**6.5**	**18.8**
SG&A*1, R&D expenses total	48.0 240.0	**47.9** **172.7**	**72.0**	46.7 155.9	**10.8**	**16.8**
SG&A*1	24.0 120.0	**25.1** **90.4**	**75.3**	22.9 76.4	**18.3**	**14.0**
R&D expenses	24.0 120.0	**22.8** **82.3**	**68.6**	23.8 79.4	**3.6**	**2.9**
Other income & expenses	7.0	**15.1**	**215.7**	(2.5)	**-**	**17.6**
Operating profit	37.0 185.0	**41.2** **148.7**	**80.4**	38.7 129.2	**15.1**	**19.5**
Finance income & costs	47.0	**42.5**	**90.5**	26.7	**59.6**	**15.9**
Profit before tax	46.4 232.0	**53.0** **191.3**	**82.4**	46.7 155.9	**22.7**	**35.4**
Profit attributable to owners of parent	188.0	**158.2**	**84.2**	133.8	**18.3**	**24.4**

Main variation factors (Y on Y)

Revenue
Increase: Prescription drugs, Royalty income, Overseas subsidiaries /export

Cost of Sales
Increase: Sales of TORII

SG&A
Increase: Selling-related expenses in US business TORII's SG&A expenses, PMI costs

R&D expenses
Increase: Former JT Pharmaceuticals Business unit and TORII's R&D expenses

Other income & expenses
Increase: Negative goodwill gain arising from the M&A (provisional treatment before the completion of the PPA)

Finance income & costs
Increase: Dividends from ViiV

*1 Selling, general & administrative expenses

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As for the contents, cost of sales was JPY 54.3 billion, which may seem a little low, representing 66.3% progress toward the full-year forecast of 72%, but in terms of the percentage increase over the previous year, it was 18.1%, which exceeds the rate of increase in revenue.

The cost of TORII, which is included in the entire four months, is higher than the cost of SHIONOGI, and we cannot solve this problem in four months; however, we are working hard to control this cost, as this cost represents a significant opportunity for improvement..

SG&A and R&D expenses increased by 10.8%, which includes selling expenses increased by 18% and R&D expenses increased by approximately 4%. It should be noted that JT's pharmaceutical business , for one month from December 1, and TORII, for three full months from October to December, are included. Looking at the quarterly results, we have made considerable progress in saving compared to the three-month contribution from TORII in the previous year and the one-month contribution from JT's pharmaceutical business, and we are beginning to see synergies here, and we expect to realize these synergies in full going forward.

In the other income section, as I mentioned earlier, there is about JPY 20 billion of negative goodwill, which is tentative, so I will discuss it again in the final report of the main accounts, but at this point, there is about JPY 20 billion as. a preliminary accounting treatment

In addition, ViiV has been doing extremely well in terms of finance income and finance costs, resulting in strong pre-tax and quarterly income.

Revenue by Segment

(Unit：B yen)

	FY2025			FY2024	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement(%)	Apr.-Dec. Results	Change (%)	Change
Prescription drugs	143.5	**86.7**	**60.4**	78.9	**9.8**	**7.8**
Overseas subsidiaries/export	61.0	**48.9**	**80.2**	43.4	**12.8**	**5.6**
Shionogi Inc. (US)	27.2	**22.1**	**81.3**	17.5	**26.3**	**4.6**
Fetroja	-	**21.3**	**-**	14.7	**44.8**	**6.6**
Shionogi B.V. (EU)	19.3	**15.6**	**81.0**	12.9	**20.6**	**2.7**
Fetcroja	-	**12.1**	**-**	9.9	**21.9**	**2.2**
Shionogi China	5.9	**4.5**	**76.1**	6.3	**(27.9)**	**(1.7)**
Others	8.6	**6.7**	**78.0**	6.7	**0.9**	**0.1**
Contract manufacturing	14.0	**10.2**	**73.0**	10.7	**(4.4)**	**(0.5)**
OTC and quasi-drug	17.5	**11.7**	**66.7**	12.7	**(8.2)**	**(1.0)**
Royalty income	261.5	**201.3**	**77.0**	186.8	**7.8**	**14.5**
HIV franchise	245.0	**193.4**	**79.0**	183.5	**5.4**	**9.9**
Others	16.5	**7.8**	**47.5**	3.3	**140.8**	**4.6**
Others	2.5	**1.9**	**75.4**	1.1	**68.6**	**0.8**
Total	500.0	**360.7**	**72.1**	333.6	**8.1**	**27.1**

Main variation factors (Y on Y)

Prescription drugs

- Increase: Sales of TORII
- Decrease: Sales of acute respiratory virus

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (US and Europe)
- Decrease: Sales of China business

Royalty income

- Increase: HIV franchise: Sales generated by ViiV
  Others
  - Royalty income from Roche
  - Royalty income related to the former JT Pharmaceutical Business Unit

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The domestic progress, which I will discuss later on page eight, is going well for us, I think. Shionogi Inc. and Shionogi B.V. are showing very strong performance and year-on-year growth.

In China, we have received approval for cefiderocol, but it has not yet been launched, which means that the negative aspects of the our legacy generic business are still weighing on performance to some extent.

In terms of royalties, ViiV's HIV franchise is doing well, as are Xofluza royalties from Roche and the one-month contribution from the former JT Group’s pharmaceutical business beginning December 1, which means the royalty was performed very strongly.

Prescription Drugs in Japan

(Unit: B yen)

	FY2025			FY2024	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change(%)	Change
Acute Respiratory Virus Infection Treatments	56.0	**27.3**	**48.7**	43.3	**(37.0)**	**(16.0)**
Quviviq	2.5	**1.1**	**44.3**	0.5	**123.8**	**0.6**
Symproic	6.5	**4.6**	**70.5**	3.8	**18.8**	**0.7**
OxyContin franchise	5.3	**3.5**	**66.3**	3.3	**6.6**	**0.2**
Others	73.2	**50.2**	**68.6**	28.0	**79.4**	**22.2**
TORII	41.2	**24.1**[*1]	**58.4**	-	**-**	**24.2**
Total	143.5	**86.7**	**60.4**	78.9	**9.8**	**7.8**

Acute respiratory virus infection treatments

- COVID-19 related product: Xocova
- Influenza franchise: Xofluza, Rapiacta

[*1] Recognized from September 1, 2025

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Page eight, please. I would like to mention here that the category of acute respiratory infections, actually Xofluza is doing very well and is very strong, but as for Xocova, the epidemic impact is not yet that huge, and the summer epidemic was not that significant, so that seems to be a bit of a negative.

However, one of our goals in bringing TORII under our group was to see how we could reduce the volatility of acute respiratory infections in sales in Japan. As you can see, in FY2025, TORII has only been on board for four months, but it is JPY 27.3 billion out of JPY 86.7 billion, which means just over 30% are acute respiratory infections. Last year, although it was very strong with JPY 43.3 billion, acute respiratory infections accounted for 55% to 56% of total sales.

TORII's products have made a full contribution, quviviq has been doing very well since the four-week prescription has become available in December and January, and zuranolone, an antidepressant, is about to be launched. I believe t sales in Japan are becoming more predictable.

Results for the Third Quarter

Growth in core businesses led to record-high sales revenue, operating profit, and quarterly profit attributable to owners of the parent company

Stable performance in HIV and overseas businesses	• Strong growth of LAI*1 products • Steady growth of cefiderocol in the U.S. and Europe
Growth of the domestic business as a key challenge in the first half of the fiscal year	• Growth of TORII's products • Stable contribution of Xofluza during the influenza season • Sales expansion through co-promotion of priority products by Shionogi and Torii
Cost management aligned with sales	• Cost management of SG&A expenses, including those related to TORII • Promotion of proactive R&D investment through prioritization

*1 Long Acting Injectable: Cabenuva, Apretude

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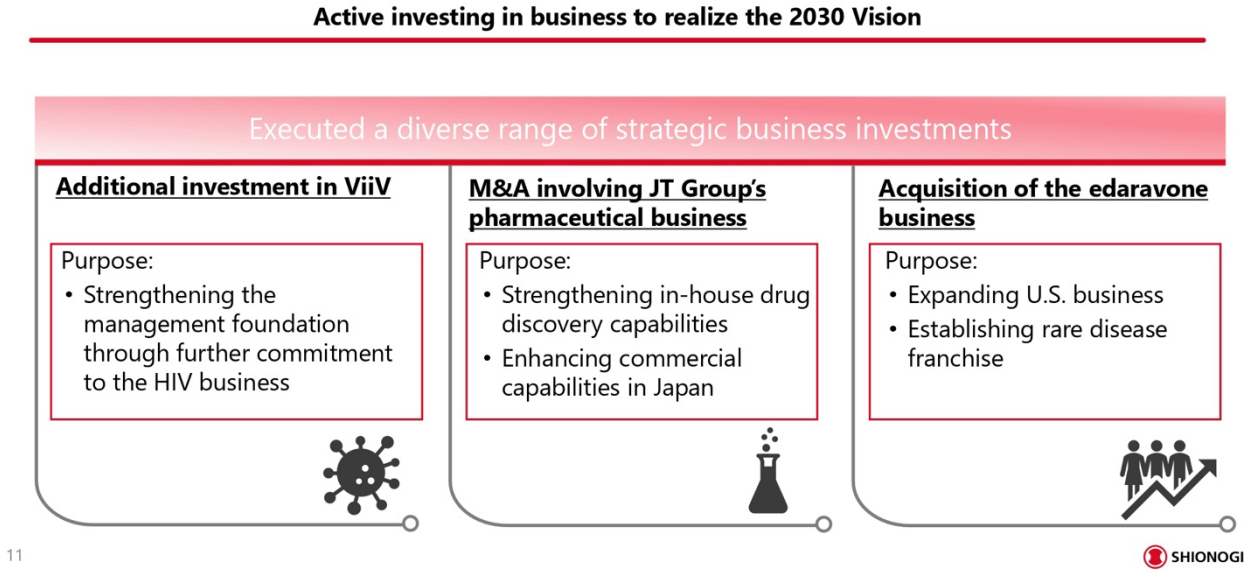
Here is a summary.

As for HIV, the growth of LAI products has exceeded our expectations, and TORII's domestic business has actually increased by 10% over the same four-month period last year. This is because. TORII's products are also growing, supported by synergies that add one to two percentage points on top of our co-promotion efforts. The market share of Xofluza is increasing significantly, and in that sense, we are seeing a very positive trend in sales in Japan.

Regarding cost management, as I mentioned earlier, sales are up, but the cost of TORII when viewed on a Year on Yera basis is lower. We intend to continue to thoroughly promote the reduction in this area. We believe it was a solid quarter where the effects of M&A were beginning to emerge.

Business Investments Executed in FY2025



Please see page 11. In addition to that, these three areas are being focused on during Q3 to the beginning of Q4. We have always wanted to make an additional investment in ViiV, if we had the opportunity, and we believe that if we increase our stake by 11.7% to 21.7%, it would be a mutually beneficial, including ViiV's commitment and ours.

Since August or September, we have been working on how to manage the JT Group's pharmaceutical business pipeline synergistically. We have been accelerating our activities since December 1, when they officially became part of SHIONOGI as the same entity. The merge for Akros, an American company, are improving steadily, and we believe that in terms of PMI, things are going very well.

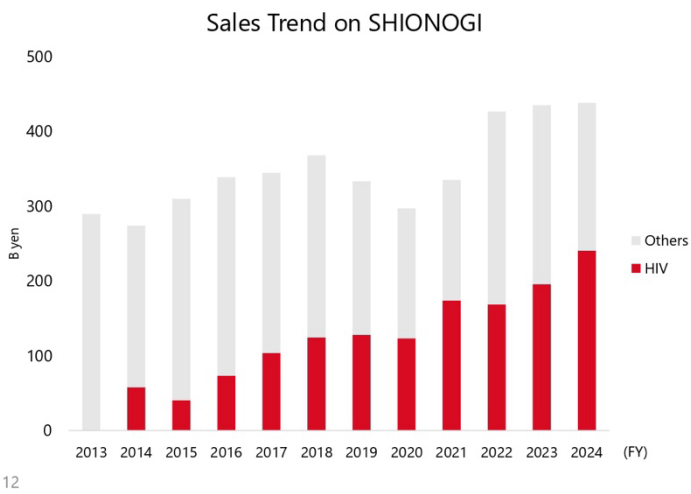
By year-end, we plan to strengthen our edaravone business. This aligns with our strategy to enhance JT Group's pharmaceutical business pipeline, which includes highly promising rare disease candidates, including zatolmilast and Pompe disease. Furthermore, acquiring the entire edaravone business franchise, particularly its rare disease operations in the US, including the associated team, represents a significant opportunity for growth.

I believe that we have taken advantage of a very good opportunity, as sales in the US will increase in the next fiscal year and beyond, and we will be able to move forward with the franchise, which focuses on rare diseases.

John will explain the current situation of HIV business and then our future plans.

SHIONOGI's Growth Driven by HIV Business

Multiple integrase inhibitors discovered by SHIONOGI have significantly contributed to growth



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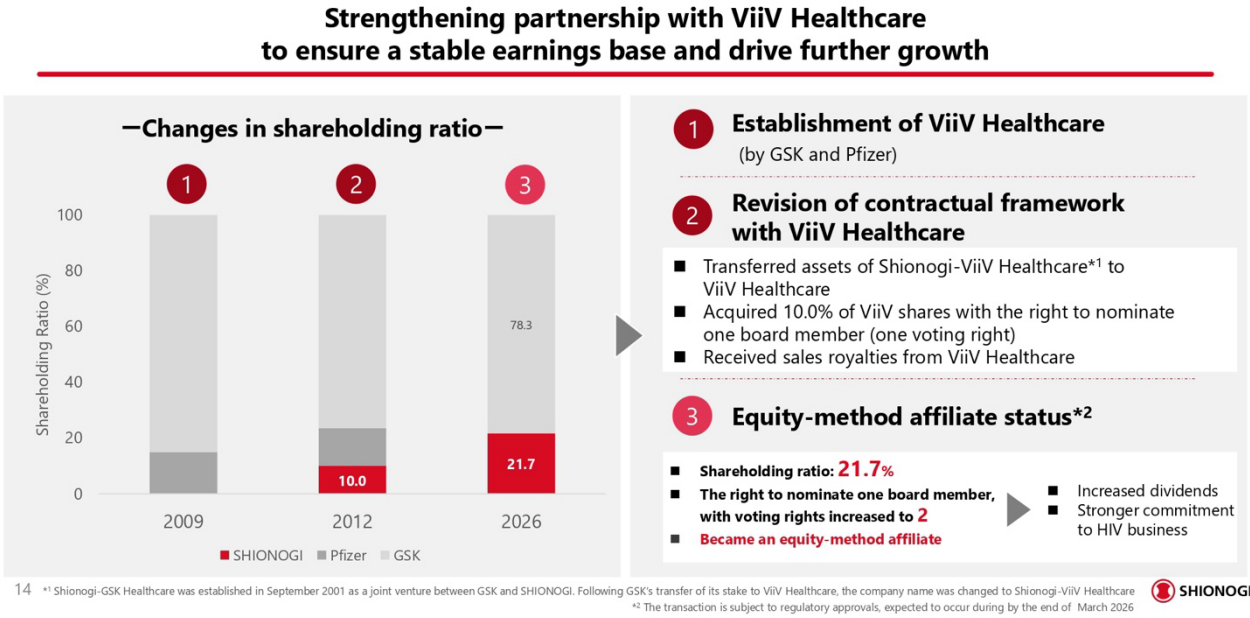
Keller: Thank you very much. So as you know, SHIONOGI's growth has proceeded alongside the strong growth of the HIV business, driven by our integrase inhibitors partnered with ViiV first with dolutegravir, which really established the integrase inhibitor paradigm, and then allowed us to follow with the long-acting formulations, which is now something extremely attractive and driven by patients and growing strongly, as you will see. And now we're moving even to the next generation of ultra long acting.

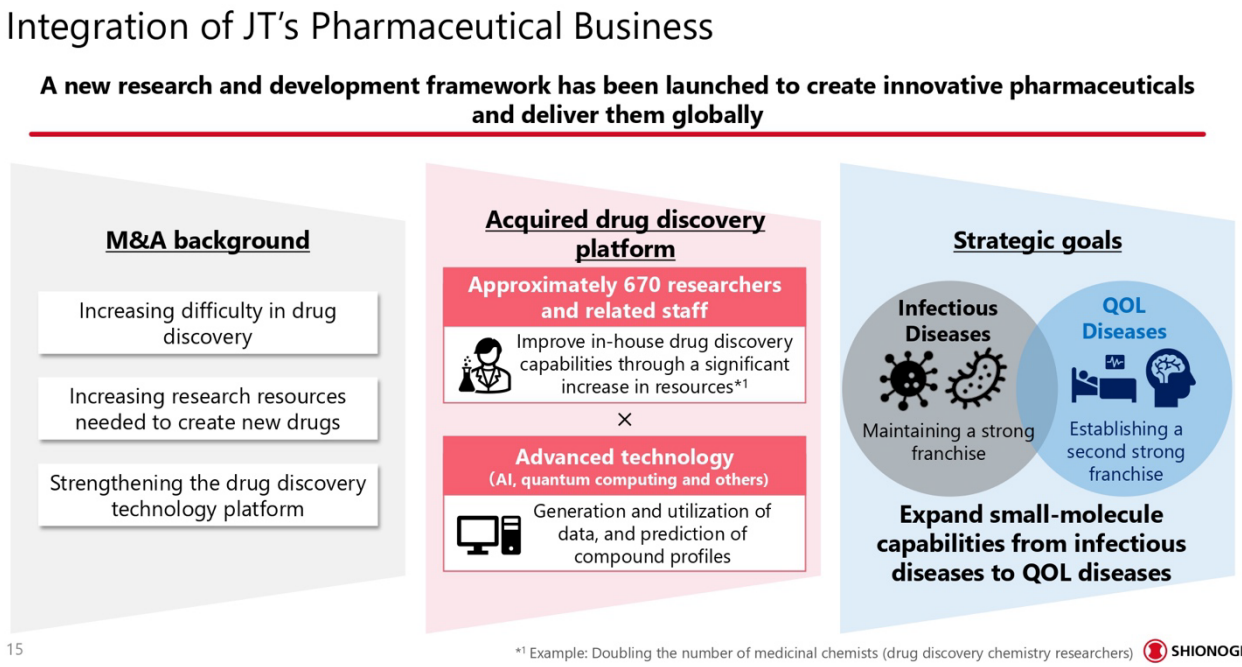
Long-acting Injectables Driving a Paradigm Shift in the HIV Market

The steady growth of the long-acting seen in the last slide, which is progressing about 50% year on year, steadily, both in treatment and in PrEP, we are now looking at progressing beyond this current long-acting to the next generation in two senses, the ultra long-acting first in terms of time, moving from two months to four months to six months, and in terms of the core integrase inhibitor of what we call S-365598, ViiV calls one, VH4524184, which we have licensed to them in 2021 and now we've seen the phase 2 oral clinical trials showing excellent tolerability as well as efficacy equivalent best in class. And we are now getting in the PK data to support every six month use, which allows us to transform this long-acting injectable treatment market yet again and again, this is the market that we've established with ViiV, and we are progressing ourselves, probably alone, for 10 years or beyond.

Partnership with ViiV Healthcare



And so looking at that future and that progress and continued growth, we had an opportunity to further strengthen and expand our relationship with ViiV, as you may know, historically, ViiV itself was established by GSK and Pfizer in 2009 at that time, we had a joint venture with GSK. That joint venture became a joint venture with ViiV. But then in 2012 we changed that to become a shareholder of ViiV and to have the royalty structure that we have been operating under since then. And also we joined myself, joined the board of ViiV at that time, along with the 10% share acquisition, now with the further acquisition of shares, bringing us to 21.7% it allows us to treat ViiV as an equity method of filling it obviously increases the dividend, and very clearly shows our commitment to the HIV business, as well as supporting two votes at the ViiV report.



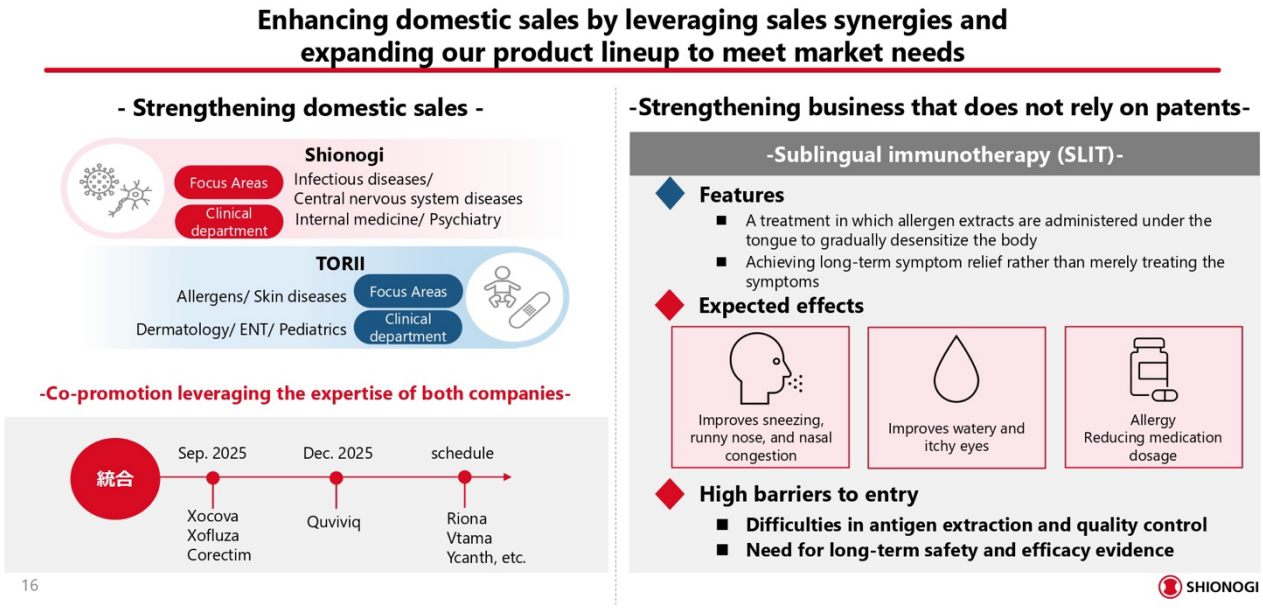
Teshirogi: Then we have another M&A with JT and Torii that is in progress. I would like to explain a little about this area, especially since JT's pharmaceutical division has been fully under the umbrella of SHIONOGI since December 1.

As I have mentioned many times, our researchers are based in Takatsuki, Osaka, and in Yokohama, but we now have nearly 700 researchers, and we have created an environment in which SHIONOGI researchers can freely use our platform, which uses AI, quantum computers, etc. I think it is exciting for JT, Torii, and especially JT researchers, and very good for us as well.

As I have mentioned many times, it has been very difficult for us to allocate all of our original resources, such as chemists, to the field of infectious diseases. We are involved in malaria, tuberculosis, NTM, and other infectious diseases, but it has been difficult to allocate resources to new areas of infectious diseases, and we because able to include individuals affected by QOL-related diseases in the combined calculations with JT. A good number of both biologists and chemists can be divided between infectious diseases and other QOL diseases, which we believe fits into this movement to create a second franchise after infectious diseases as soon as possible.

In particular, we are also holding joint events such as research presentations, and arrangements are under way to fully implement this starting this February. Regarding this, I believe the PMI in research and development domain is progressing with virtually no disruption.

Integration with TORII



It is the synergy with Torii that I mentioned a little earlier.

We are starting with where we can, so we are doing co-promotion, as you can see on the bottom left of that page. This will not only increase the number of products but also get people from Torii to do Xocova and Xofluza in the dermatology and otolaryngology areas, for example, which we have not been doing. We use Corectim in the field of internal medicine. In response, we would add Quiviviq, and then increase the Torii's pipeline of Riona, Vtama, YCANTH, etc. We will also be launching ZURZUVAE, and as soon as we are fully prepared, we are considering implementing a co-promotion for this product as well. We believe the synergy in our domestic sales activities have been working very well.

In addition, we have finally received approval for our vaccine business and are in the process of applying for approval as a platform vaccine, so I think we will be able to sell vaccines little by little in the near future. We have finally received approval for the vaccine business and are in the process of applying for approval as a platform vaccine.

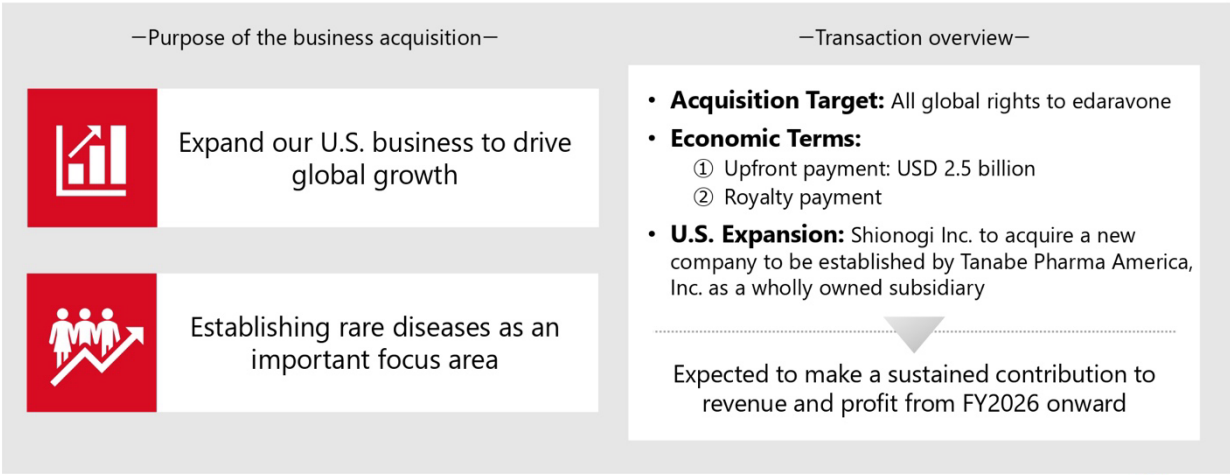
Regarding this SLIT, we believe generics will be extremely difficult to develop, we expect very few will emerge, due to manufacturing challenges and the complexity of achieving bioequivalence. However, we believe this business can be grown.

Especially in our country, when former Prime Minister Kishida was in charge of cedar pollen allergies, he said that this was already close to becoming a national tragedy, and Japan as a whole has been thinking about how to solve this problem. We were able to get that franchise in its entirety.

In terms of increasing the depth of our business to avoid patent cliffs as much as possible, as we have said in the past, the acquisition of SLIT by Torii was a very significant addition to the HaaS business.

Overview of the Edaravone Business Acquisition

Acquiring full rights to edaravone and a U.S. commercial platform to accelerate global growth beyond infectious disease areas



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Next is edaravone. Regarding this, we are aware that we are mostly buying American business. Of course, there are other countries, but basically, we would like to focus on rare diseases in the US, and together with cefiderocol, we would like to bring sales to a billion plus as quickly as possible, and then hope for the next growth. We are currently operating under the assumption that nearly all of individuals currently engaged in sales and related activities will be joining our organization.

We believe we are almost certainly on track for the April 1 turnkey, and while we are pursuing the PMI quite aggressively, we also believe it is progressing smoothly at this point.

Innovative Therapeutic Drugs Addressing Unmet Needs

A marketed product with established safety and efficacy, expected to deliver stable growth going forward

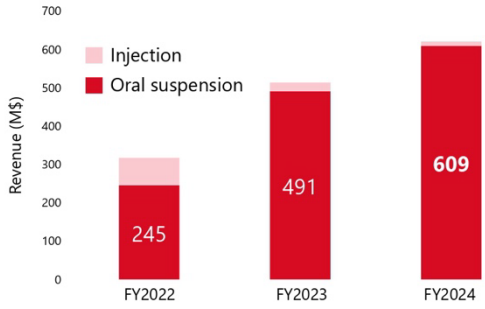
—Features of edaravone—

- **Indication:** Treatment of amyotrophic lateral sclerosis (ALS)
- **Modality:** Small-molecule drug
- **Formulations:**
  - Injection (U.S. launch: 2017)
  - Oral suspension (U.S. launch: 2022)

Enhancing QOL through the oral suspension

- ✓ Provides an option for patients with dysphagia
- ✓ Allows administration without requiring clinic visits
- ✓ Avoids injection-related pain

—U.S. Sales trend of edaravone (Radicava)*1—



Growth of the oral suspension is driving overall Radicava expansion

*1 Tanabe Pharma's sales performance

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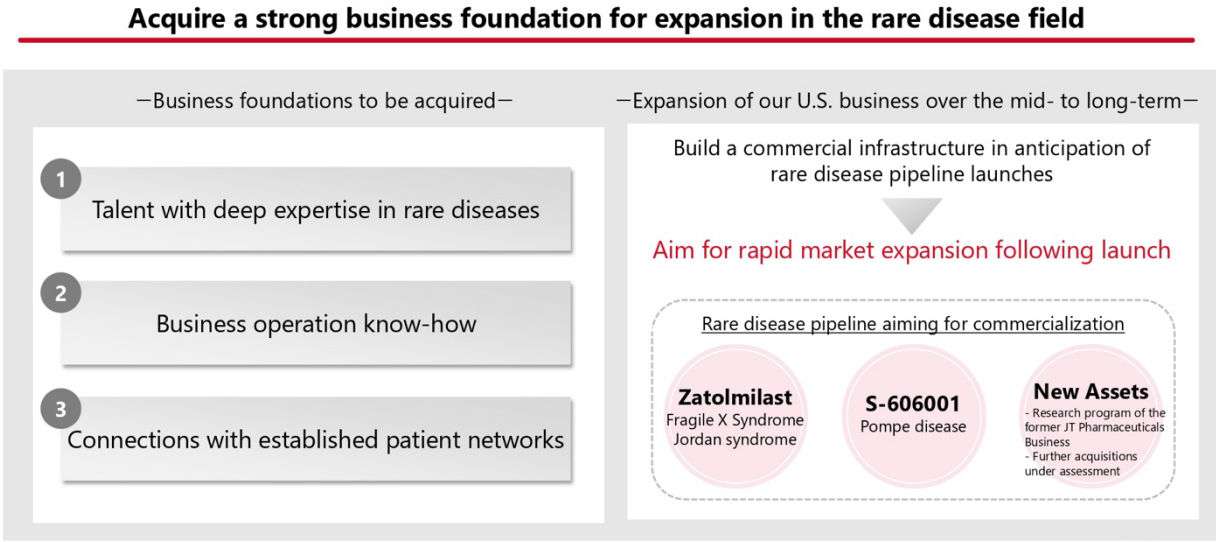
I am sure that many of you, including analysts, are more familiar with this area, but the Company has created a very strong market by treatment of ALS patients with this oral suspension drug, and it is still in the process of growing. By taking this over, we are making a major commitment to this area.

We believe that our negotiations and discussions with the FDA regarding zatolmilast are going well. We will open the key very soon and get the results, and if they are good, we would like to submit the application for approval.

In preparation for this, SHIONOGI has actually begun to take in many people for rare diseases. We carefully evaluated each individual and selected the best candidates, but we struggled to recruit in groups of 10 or 20. With this edaravone team, we were able to secure an entire team like that. I believe this was truly beneficial for both parties, and we intend to move forward with it.

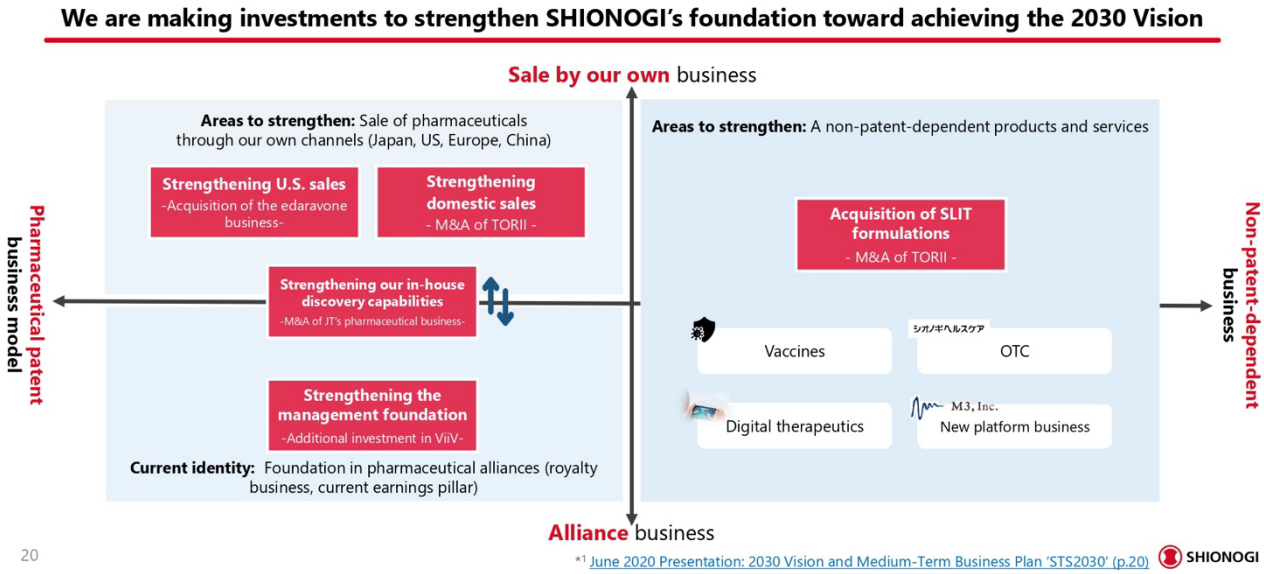
Toward Establishing a Rare Disease Business in the U.S.



SHIONOGI

As I mentioned earlier, of the field force members who are really working in the field, we think we have about 30 to 40, and the remaining members are functioning for a rare disease franchise, and I believe that we have established the foundation for connecting them to the next rare disease team with almost no overlap.

Positioning of Business Investments within the Corporate Strategy*1



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*1 June 2020 Presentation: 2030 Vision and Medium-Term Business Plan 'STS2030' (p.20)

SHIONOGI

The last page, page 20, is a little list of what I have said so far. M&A with JT and Torii will enhance research and sales in Japan, especially in a way that is not biased toward so-called seasonal or infectious diseases only.

In addition, by acquiring the edaravone business in the US, we are on track to achieve sales of USD1 billion in the US and have created a large footprint in the area of rare diseases, which we had hoped to strengthen.

In addition, the HIV business is the mainstay of our earnings, and as John mentioned, the reason I decided to undertake such a large M&A as a company was because S-365598 (VH4524184) was doing very well, which increased our confidence in the Company and led to such aggressive activities. Around the middle of 2030, with cabotegravir and such, if VH4524184 moves, we should be able to secure a fairly strong base royalty through the mid-2040s. Therefore, regarding other growth areas, we decided it was acceptable to take risks and be proactive now. That's why we moved quite aggressively in FY2025.

I believe this past year has been one where we have advanced our efforts in the direction we intended to pursue without significant deviation from our desired course. Including this, we aim to continue our growth beyond FY2026.

Now, regarding the pipeline, John will be presenting some of the highlights of this Q3.

Major Development Projects: Infectious Diseases

Project	Indication	Current stage*1	Update
Ensitrelvir	COVID-19 treatment	Submission	
	COVID-19 treatment (age 6-11)	Submission	
	COVID-19 PEP	Submission	
	COVID-19 treatment (age 0-5)	Phase 3	**FPI*3 achieved**
S-268024	COVID-19 (JN.1 vaccine)	Submission	**Submitted in Japan**
Cefiderocol	AMR*2 (Pediatric・Gram-negative bacterial infection)	Phase 3	
Olorofim	Invasive Aspergillosis	Phase 3	**LPI*4 achieved**
S-337395	RSV infections	Phase 2b	
S-892216	COVID-19 treatment (Oral pill・treatment)	Phase 2	
	COVID-19 (Long-acting injectable・pre-exposure prophylaxis)	Phase 1	
S-743229	AMR (Complicated urinary tract infection)	Phase 1	
S-649228	AMR (Gram-negative bacterial infection)	Phase 1	**Obtained the topline result of Phase 1**
S-567123	COVID-19 Prevention (Broadly protective coronavirus vaccine)	Phase 1	**FPI*3 achieved**

*1 The current stage indicated refers to the most advanced stage in any region, excluding countries or regions where the product has already been launched, and is not based on any specific region *2 AMR：Antimicrobial Resistance *3 FPI: First Patient In *4 LPI：Last Patient In

SHIONOGI

Keller: So now to close with a few updates on pipeline progress, first in infectious disease for ensitrelvir, we have the first patient in in pediatric phase 3, in very young children, zero to five. For our vaccine, COVID-19 vaccine platform, we have submitted for the JN.1 strain, once that's approved, that will establish our COVID-19 vaccine platform in Japan and allow us to routinely update strains as necessary. With respect to olorofim our antifungal and invasive Aspergillosis, we have completed last patient in in the phase 3 study. And so that has, after time to recruit, has progressed much more quickly in the past year, and we're being excited to see the results from that. And then S-649228, further advancement of our fight against antimicrobial resistance with gram negative antibiotics inhibitor. And for that, we have gotten the Phase 1 Top- line, which allows us to proceed the program further and then with the next S-567123, our broad coverage vaccine, so called universal vaccine for COVID-19, first patient in.

Major Development Projects: QOL Diseases with High Social Impact

Project	Indication	Current stage*1	Update
Zuranolone	Depression	Approved	**Approved in Japan**
Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	
Zatolmilast	Fragile X syndrome	Phase 2/3	
	Jordan syndrome	Phase 2	**LPI achieved**
Redasemtide	Dystrophic epidermolysis bullosa	Phase 2	
	Acute ischemic stroke	Phase 2b	**LPI achieved**
SASS-001 (S-600918 + Combination medicine)	Sleep apnea symdrome (central component)	Phase 2	
SASS-002 (Sulthiame)	Sleep apnea syndrome (obstructive)	Phase 2	
S-606001	Pompe disease	Phase 2	
S-309309	Obesity	Phase 2	
S-531011	Solid tumors	Phase 1b/2	
S-151128	Chronic pain	Phase 1b	

*1 The current stage indicated refers to the most advanced stage in any region, excluding countries or regions where the product has already been launched, and is not based on any specific region

Outside of infectious disease, we have gotten the last patient in for azatolmilast, last for our very ultra rare disease, Jordan syndrome, while with fragile X in parallel, we are progressing discussions with FDA around endpoints, after which we will complete the analysis and proceed from there. For servant alone, we have secured the Japanese approval, and for redasemtide in stroke, we have achieved last patient in again, a very complex study, but now this allows us to complete the study and progress the results. Thank you.

Question & Answer

Kyokawa: Okay, we will move on to the Q&A session.

Now, the first one, Mr. Yamaguchi from Citigroup, please.

Yamaguchi: I'm Yamaguchi. Thank you very much. Thank you very much for your presentation.

First of all, you mentioned negative goodwill, which is not included in the Company's forecast, and 20 billion yen is shown at this point, and if it remains unchanged, 20 billion yen will remain for the full year as well, but not for the next fiscal year and thereafter. Is this something like that?

Kudo: I'm Kudo, Head of Business Strategy Division, and I will answer your question. As for this negative goodwill gain, it comes from JT Group's pharmaceutical business. The PPA procedure is still in progress, and the figures recognized in Q3 are only provisional, so the final figures will be available at the end of the fiscal year.

We are currently examining whether or not the amount will be the same as we are now presenting. This will not affect the next fiscal year as a gain.

Yamaguchi: I see. Thank you very much. Regarding zatolmilast, it felt like there might or might not be further developments, but timing-wise, especially for Fragile X syndrome, I think it's getting a lot of attention. Do you think we can see a clear window for when things might start moving?

Keller: We selected Jordan's syndrome as an additional indication to Fragile X syndrome because both conditions share a common feature of reduced cAMP levels in the brain, and this aligns well with the mechanism of action of zatolmilast, which increases cAMP signaling. For this reason, we judged Jordan's syndrome to be an appropriate addition. In addition, we expect a high degree of synergy between the two indications, as we are planning similar study designs and similar clinical endpoints for both. Therefore, we believe zatolmilast has the potential to be effective in both diseases.

We will continue to focus on zatolmilast and advance its development in these two rare diseases for the time being. However, we also intend to explore other rare diseases that have a similarly strong scientific rationale.

Teshirogi: Basically, we are going to communicate in Q1 of FY2026 about where we are going as a result of the key break in some form.

Yamaguchi: I see. Also, there were deals, edaravone and ViiV, this time that moved a lot of cash flow. In the next fiscal year and the fiscal year after that, each of these will be on board, so it seems normal that profits will increase considerably. In your company's view, there will be some costs for both, but do you see a significant contribution to profits in the next fiscal year and the year after that?

Teshirogi: Yes. That's what I think.

Yamaguchi: I see. Finally, I'm a little confused about the edaravone exclusivity, though. As for your company, do you have any guidance as to when you are looking at this yet?

Teshirogi: Yes. There is none now. As you all know that the part as a rare disease is clear until 2029. Regarding other matters, we are certainly working on them as well, but as for how we will present our case, we are not currently disclosing that information.

Yamaguchi: I understand. That's all from me. Thank you very much.

Teshirogi: Thank you very much.

Kyokawa: Next, Mr. Ueda of Goldman Sachs Securities, please.

Ueda: My name is Ueda from Goldman Sachs Securities. I would like to start by asking you to tell us a little more about the thinking behind ViiV's part of the additional investment.

Although there are differences in business strategy, Pfizer has decided to sell its stake in ViiV, and I wonder that ViiV's profit trend after the dolutegravir patent expiration will be important for your company's future return on investment.

As for the idea behind the addition of investment, I am not sure if it can be considered as an indication of expectations for franchises of long acting, as you mentioned a little earlier. Also, with the change in the composition of shareholders, can you explain what we can expect in terms of collaboration in addition to the financial impact?

Keller: While we cannot fully predict Pfizer's thinking, their decision is surely the result of a process in which they invested substantial time and consideration.

Although this deal is dynamic in nature, we view it as an outcome of the joint venture originally established with GSK. Today, this has evolved into ViiV Healthcare, where we have a very open and highly collaborative partnership. We believe this relationship will continue to strengthen and allow even greater flexibility going forward.

Teshirogi: We have always wanted to become an equity method affiliate if we had the chance. Of course, there are some changes to IFRS, so after 2027, we will be below OPI.

However, there is no doubt that we can make it consolidated, which will be a very significant contribution to final profits. Furthermore, as John just mentioned, returning to a de facto two-company board with GSK will also mean faster strategic decision-making and we'll gain our influence. This is our core revenue base, so naturally, if (S-365598(ViiV Healthcare development code: VH4524184) proceeds smoothly, royalty terms will become considerably more favorable.

In addition, we wanted to strengthen the foundation of the business, so we decided to invest in the Company as an equity method affiliate, which had a certain significance for us.

Ueda: Thank you very much. Second, I also would like to ask you about the business trend in the HIV-related area.

I believe performance has been exceptionally strong, exceeding expectations, as evidenced by GSK raising its outlook in the previous quarter. Could you comment on the background to this, and also whether there is any risk of changes in the HIV treatment business environment due to shifts in competition, such as Biktarvy recently becoming subject to Medicare drug price negotiations under the IRA?

Keller: No, we will continue to focus on expanding our LAI formulations. Biktarvy is an oral regimen. With the implementation of the IRA in 2028, there may be changes affecting oral regimens like Biktarvy, but we do not expect any impact on LAI formulations. We see the HIV treatment market for LAI formulations as being driven by patients, without reimbursement restrictions, and therefore not subject to the kinds of changes that may occur with oral therapies.

Accordingly, our focus is to continue expanding our LAI formulations, moving from a four-month to a six-month option. We want to increase the number of patients using LAI treatments, as it is very rare for a patient who starts an LAI regimen to return to an oral one.

Ueda: I see. Thank you very much. That's all from me.

Kyokawa: Thank you very much. Continuing on, Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi: I am Hashiguchi from Daiwa Securities. Thank you very much. Thank you very much for your presentation.

I would like to know again how you view the pipeline situation as a whole and how you plan to invest and work on future expansion.

Given the substantial investment made in acquiring edaravone, I believe you undoubtedly still possess a pipeline capable of effectively leveraging this foundation. However, further expansion could make the investment even more effective.

In that sense, how do you plan to utilize this foundation in the future? One option would be to wait and see how drug discovery develops in the future, but I would like to ask again what you think about the possibility of acquiring items that have already been finished to some extent from outside sources.

Keller: Yes, I see. As always, we continue to place high expectations on and actively invest in our own drug discovery efforts. With the acquisition of the edaravone business, we have been able to clearly establish a foundation in the rare disease area. In addition to the development assets carried over from the former JT group pharmaceutical business, we are of course focusing on the late-stage rare disease programs as well, and we intend to keep working on expanding our pipeline.

Following the integration of the former JT pharmaceutical business, we plan to continue strengthening our commitment to rare diseases—both internally and externally—while also building a pipeline in areas such as allergy and immunology.

Hashiguchi: Thank you very much. At the briefing three months ago, you explained that you were considering three or four large deals. I don't think you have reached the four cases yet, but I would like to know if there are any ongoing ones left, and if so, what ones are still under consideration. If you can comment on the time frame, please let me know.

Teshirogi: Some are still going on. However, as for the timing, we have disclosed PMI on JT Group’s pharmaceutical business and Torii, and I think it has gone very well. We have been able to work on it with little or no distraction, and that is what we are trying to do with the edaravone business as well, and we hope to do so somehow based on our experience.

As Mr. Yamaguchi mentioned, what we purchase properly leads to the proper results, and I think you will agree that we can see that in Torii's case. We would like to go through the process one by one to make sure that they are correct. I don't think it is very likely at this point that we will be able to add any new growth investments during the fiscal year, but we will continue to look for opportunities and partners since we need them if we want to do that.

The most important priority for the Company is that everyone can see that we have properly set up these three projects, including ViiV's, in line with our direction, and that they are working properly. I think it is the most important thing for everyone to see that we are moving in the right direction.

Hashiguchi: I understand. Thank you very much. That's all from me.

Teshirogi: Thank you very much.

Kyokawa: Thank you very much. Continuing on, Mr. Seki of UBS, please go ahead.

Seki: This is Seki from UBS. Thank you very much.

First, in terms of your approach to shareholder returns, I believe that these three deals will probably result in a considerable increase in EBITDA or operating profit in the next fiscal year. Since debt may also be used, what kind of shareholder returns are likely to be made in the next fiscal year and beyond that will allow us to realize this significant growth together?

Teshirogi: Our basic stance is that we have increased dividends for 14 consecutive years, and my original intention to continue that trend as long as possible has not changed. I think we have a certain direction in mind, although we are still in dialogue with the market and the Board of Directors.

Regarding share buybacks, as Mr. Hashiguchi also inquired earlier, we are not without options under consideration. How to maximize the value of any shares we purchase, and how to translate that into tangible figures and growth, is of paramount importance. While the high priority of this is beyond question, if such opportunities gradually diminish and autonomous growth becomes increasingly robust, then naturally, share buybacks or other forms of shareholder return would come onto our agenda.

This is really something we would like to think about in constant conversation with our Board of Directors as well as with the market.

Seki: Thank you very much. Secondly, in terms of accounting, you mentioned that there is no guidance on the patent term for edaravone, but I heard that there is an amortization period, and also that there is amortization of intangible assets with this acquisition of ViiV stock. I think the guidance part, or rather, the forecast for the next fiscal year will be slightly skewed depending on the amount, so will the guidance there be given before May?

Kudo: With regard to edaravone, and also with regard to ViiV, the PPA procedure can basically be considered for one year. Currently, we believe that we will be able to disclose the situation at the end of H1 of next year or at the end of the fiscal year. We are still in the process of examining the figures, so we are unable to present them to you.

Seki: I see. Thank you very much. Third, CEP Teshirogi mentioned earlier that JT has a very interesting rare disease franchise. Could you elaborate on it a bit more?

Teshirogi: We recognize that market participants likely also desire to see a consolidated one table presented at an early stage, outlining the pipeline of SHIONOGI, the former JT pharmaceutical business, and Torii in the list, and clarifying the priority and approach for advancing these projects as part of the new SHIONOGI family.

For our part, we would prefer to present our current thinking on R&D at a separate conference or the like a little later than the May or June financial results, since it would be complicated if we present them together with the financial results.

Rather than rushing through it in an hour or two, I believe it would be better to take this opportunity to thoroughly discuss these matters with everyone. This timing coincides with the emergence of the new GSK CEO's various perspectives. We can then present how HIV will be addressed, how our consolidated pipeline will evolve, and what priorities we will pursue based on those perspectives.

Seki: Thank you very much. Also, sorry, a last quick question, I would like to ask John. Regarding the discussion with the FDA, I understand that you are discussing the endpoints of zatolmilast. Is it possible to reach an agreement with the FDA?

Keller: Regarding the originally pre-specified endpoints, we had very complex endpoints based on KOLs etc.

Initially, the FDA expressed the view that the endpoint was not favorable and that its validity had not been sufficiently demonstrated. In response, we decided to conduct further validation; however, we found that the endpoint did not in fact show a meaningful correlation with other endpoints that we had also prepared.

We have now shared these findings with the FDA and are currently in discussions regarding which of several potential endpoints the FDA would place emphasis on, and what is most important in demonstrating clinical benefit and impact for patients. As this is a therapeutic area in which there are no approved drugs or established endpoints to date, we will continue to engage in careful and constructive discussions with the FDA.

Seki: Thank you very much. That is all.

Kyokawa: Thank you very much. Continuing on, Mr. Wakao of JPMorgan Securities, please go ahead.

Wakao: My name is Wakao from JPMorgan Securities. Thank you very much. I would like to start about what Mr. Seki has just mentioned. I understand that zatolmilast's current negotiations, or rather discussions, with this FDA will eventually increase the probability of success of this trial itself, is that correct? Isn't it something like that?

Keller: Yes. we are doing everything we can to obtain a positive outcome from the FDA. What matters most is identifying what the FDA views as having the greatest impact on patients and what constitutes the appropriate endpoints.

Wakao: I see. Secondly, you are planning to acquire six months of PK data for LAI formulations. Are you going to release it at CROI? Could you please let us know if there was a specific timing for any announcements to be made externally?

Keller: The decision regarding the timing of external data disclosure will be made by ViiV Healthcare. Once they determine the appropriate timing for disclosure, we will inform you accordingly. Naturally, the data are being managed with great care. In some cases, it may take more than six months to review all the data, and if the study design requires a six-month exposure period, the trial itself will necessarily take the full six months. Therefore, identifying the appropriate timing and venue for disclosure is a matter of great importance for ViiV Healthcare.

Wakao: I see. And you also explained that including Torii Pharmaceutical you have been managing costs appropriately.[inaudible]And you explained that including Torii Pharmaceutical you have been managing costs appropriately. When we look at your plans for the next fiscal year, can we assume that you are in a position to reach a level that will give us the impression that you are making solid cost reductions, including Torii?

Teshirogi: Regarding the cost aspect, since some measures, like adding new manufacturing facilities or collecting stability data, yield immediate results while others do not, we will proceed gradually. Regarding SG&A expenses and R&D expenses, we are currently beginning to formulate our budget based on guidance that we will control these costs at this level on a combined basis. Therefore, you can assume the budget will be structured in a way that aligns with what you would likely expect.

Wakao: I see. Lastly, I'd like to confirm the impact on next year's P&L when ViiV becomes an equity method affiliate. I am wondering what will happen to net profit in the end, since the equity method of accounting will

increase operating profit and on the other hand, dividends will no longer be recorded. Can I see it working positively on the net basis? Let me just check there.

Kudo: As you mentioned, regarding accounting treatment, the equity share of ViiV's net profit is recorded as investment income in the denominator under other income, while dividends are not recorded on the P&L.

As for the equity method profit, I am sorry to repeat, but it depends on the results of the PPA, and we are not in a position to tell you what impact it will have at this point.

Wakao: But the profit will come out on the net basis. So, I guess there are various factors that can affect it, but that said, I wonder if it will be profitable or not. Is that a situation that you cannot comment on yet?

Kudo: It is not unprofitable. We have not yet seen how much the increase will be or anything like that.

Wakao: So, we can understand that it is positive for current net profit?

Kudo: Yes. It is as you say.

Wakao: Thank you very much. That is all.

Kyokawa: Thank you very much. Next, Ms. Sogi of Bernstein, please go ahead.

Sogi: Thank you very much. First, regarding edaravone's acquisitions.

I understand that you have not yet disclosed how long the patent protection will last. However, considering the amount of acquisition, the current sales, and the fact that you acquired not only their products but also the organization, I think that the deal itself will not be positive if the protection ends with the orphan in 2029. Please tell me again about your thinking.

Teshirogi: I think it is normal to think so in general terms.

Sogi: I see. I understand. Thank you very much. Does it mean that we can assume that there is a fairly high probability, a high probability, that there is also protection after that?

Teshirogi: I will tell you when there is a right time to tell you. I would like you to understand it.

Sogi: I see. Thank you very much. Question for John. With respect to the Phase 3 study in Fragile X syndrome, is it correct to understand that the study has already been completed, that the pre-specified primary endpoint was not met, and that alternative endpoints are now being considered based on the data obtained? In addition, is it correct to understand that future disclosure would be made at the timing of the submission of a New Drug Application, or upon FDA acceptance of the application?

Keller: No for the first point. We are currently in the process of discussing the endpoint, and we will proceed with the analysis thereafter. On the second point, once the analysis is completed, we will determine whether to disclose the results of that analysis, including whether or not to make the analysis public.

Sogi: Thank you very much.

Kyokawa: Thank you very much. Continuing on, Mr. Yamakita of Jefferies, please go ahead.

Yamakita: My name is Yamakita from Jefferies. Thank you very much.

My first question, first of all, what are your thoughts on financial leverage? I wonder if you will consider using debt in conjunction with this series of acquisitions, but your company has an abundant cash flow, so I believe that you can pay back the debt as soon as you want to. Can you give us any thoughts on how much of this financial leverage you would allow or maintain over the medium to long term? If there is any thought, please let me know.

Kudo: Kudo will answer the question. This time, we plan to temporarily secure funding through a bridge loan for an amount nearly matching the two investment projects, followed by permanent financing arrangements considering financial soundness and other factors. However, as other projects are also under review, we intend to consider these aspects while taking into account the overall situation as it becomes clearer. At this point, we are still considering the whole picture as it is not yet available.

Yamakita: I see. Thank you very much. Also, let me confirm one more point regarding the US cost outlook. I understand that you said earlier that you have replenished the Tanabe Pharma America, Inc. staffing and that there is enough staff for rare diseases and that this should be fine for now.

In expanding the US business in the next fiscal year and the fiscal year after that, will you simply add up the costs for the next fiscal year, or will you expand marketing and personnel investments for further expansion in the fiscal year after next? Could you tell me something about how those US costs are increasing?

Teshirogi: We are wondering if at least cefiderocol, plus existing products, plus edaravone, would take some synergy from what we are currently using. Frankly speaking, the wild card for us is how much we should invest in ensitrelvir's PEP as a capital project. This is currently a major point of discussion within our organization.

We are confident that we can get PEP approval at this point. However, it depends entirely on the scenario, how much to invest and how far to pursue it.

Other than that, I think we are relatively good at containing costs, so I think it is safe to assume that it will not be anything more than a strange addition to the total.

Yamakita: I understand. That's all from me. Thank you very much.

Kyokawa: Mr. Matsubara, please go ahead.

Matsubara: I am Matsubara from Nomura Securities. Thank you very much.

The first point is that I would like to know more about QUVIVIQ. I would like to ask what the current prescription situation is after restriction on two-week prescriptions has been discontinued. I'm wondering if we can see the expansion of prescriptions in the explanation as well, in terms of copromotion with Torii. Please tell us how you see the current trend toward the achievement of this fiscal year and even more so for the next fiscal year.

Teshirogi: So far, the response has been very good, especially this month. Of course, daily sales are uneven, but if we can achieve daily sales of JPY40 million or JPY50 million as quickly as possible, this would translate into an annual revenues of approximately JPY10 billion to JPY15 billion. We have begun to see those daily sales levels in recent days toward the latter part of January, so I believe it is now usable to a reasonable extent.

Of course, competitors' products are also very active in the market, so it is not an easy market, but for now, especially after January, we believe the business is progressing broadly on track.

Matsubara: Thank you very much. Am I correct in understanding that if so, you are gradually gaining prescriptions compared to Dayvigo?

Teshirogi: Yes. Dayvigo is still strong in terms of acquiring the number of ongoing patients, however, in terms of new patients and switching prescriptions, I think it is doing quite well compared to the other competitors.

Matsubara: Thank you very much. The other question I would like to ask is about the market environment for HIV. I am thinking about the possibility of new variants of HIV emerging, although it may be a little early to say that, since President Trump has just cut off the aid. In this context, I would like to know if the market environment for this HIV PrEP and treatment has changed, if any, and if you can tell me about that.

Teshirogi: There are not many signs of change at this time. As you mentioned, while PEPFAR and USAID have significantly scaled back their activities in the US, there are still a few visible examples, though they are quite scattered. As you know, bictegravir, dolutegravir, and cabotegravir are quite similar in structure when it comes to IP litigation originally, so-called second-generation integrase inhibitors. It is cross-reacting, and as for our S-365598 (ViiV development code: VH4524184), it has a completely separate resistance profile.

The good news for the world is that even if something happens, there is a backup. However, at this point, we do not recognize that there is a clear, global increase in resistance against drugs known as the second-generation integrase inhibitors.

Matsubara: I understand. Thank you very much.

Kyokawa: Thank you very much. This concludes Q3 of fiscal 2025 financial results briefing session of SHIONOGI & CO., LTD.

Thank you very much for your participation despite your busy schedule.