SHIONOGI & CO. LTD.

Q3 Financial Results Briefing for the Fiscal Year Ending March 2021 Conference Call

February 1, 2021

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Business Impact of COVID-19

Impact of COVID-19 on 3Q FY2020 and Our Response

- **Supply chain**
  - Continued to secure inventory, and increased monitoring of manufacturing of active pharmaceutical ingredients (APIs) and products by suppliers and CMOs so as to be prepared for major environmental changes stemming from the spread of COVID-19
  - From a national security standpoint, participated in a project to promote the domestic manufacture of raw ingredients of pharmaceutical agents for which Japan is currently heavily dependent on overseas production (received a grant from the Ministry of Health, Labour and Welfare to ensure stable supplies of pharmaceuticals)
- **Promotion**
  - At the clinic, the proportion of face-to-face meetings with physicians has recovered to around 70% of the pre-COVID-19 level, but it remained at a low level at large hospitals so far
  - Providing information virtually, in an efficient manner, through web-conferences and e-details, in combination with face-to-face or online meetings, depending upon the needs of each medical institution
  - Continuing to train sales reps for comprehensive understanding of disease, in collaboration with the Integrated Disease Care Division
- **R&D**
  - Focused resources on COVID-19-related projects, and commenced clinical trials of vaccine as planned
  - No significant impact on development timeline for 8 core projects* and, or for any other projects, in the 3rd quarter**

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* See Appendix p.19 ** See Appendix p.35-37

Hosogai: I will explain the third-quarter financial results of FY2020 according to the conference call material. I will report the results following the agenda described on page 2.

First, on page 4, I will explain the impact of the COVID-19 pandemic on our business.

We have described the impact on the supply chain, domestic promotion, and R&D in the third quarter. No major changes have taken place from the second quarter. I will explain about R&D activities again later.

Financial Results (Consolidated)

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Revenue	318.1	**224.4**	70.5	254.8	(11.9)	(30.3)
Operating profit	133.2	**102.2**	76.7	106.7	(4.2)	(4.5)
Core operating profit**	108.5	**80.0**	73.7	104.4	(23.4)	(24.5)
Profit before tax	159.6	**116.8**	73.2	123.6	(5.5)	(6.8)
Profit attributable to owners of parent	119.7	**86.1**	71.9	94.3	(8.7)	(8.2)

- **Sales of infectious disease drugs, mainly influenza franchise, decreased but that of other products were almost as expected**
- **Sales and profits decreased year on year due to aggressive investment in R&D in addition to the impact of transient earnings of the previous year and foreign exchange**

Exchange Rate (average)	FY2020 forecasts (Oct. 30)	FY2020 Apr.-Dec. results
USD ($) – JPY (¥)	107.00	106.11
GBP (£) – JPY (¥)	135.00	136.29
EUR (€) – JPY (¥)	120.00	122.45

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* Converted from JGAAP to IFRS
** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

On page 5, I would like to report the consolidated financial results.

For the period from April to December, as indicated in a red bracket in the middle, revenue was JPY224.4 billion, reflecting 70.5% of the full-year forecast and down JPY30.3 billion from the same period last year. On the other hand, operating profit was JPY102.2 billion, indicating 76.7% of the full-year forecast and down JPY4.5 billion from the same period last year. Core operating income was JPY80 billion, achieving 73.7% of the full-year forecast and down JPY24.5 billion from the same period last year.

Profit before tax was JPY116.8 billion, representing a 73.2% progress toward the full-year forecast and down JPY6.8 billion from the same period last year. Profit attributable to owners of parent was JPY86.1 billion, reflecting 71.9% of the full-year forecast and down JPY8.2 billion from the same period last year.

A summary of the results is described on the left, inside a blue bracket. In the first point, we comment on the progress rates toward the full-year forecast. Revenue finished at the indicated level as a result of significant changes in the situation around infectious disease drugs, such as influenza-related products. We believe the other reported items, such as operating profit, are not meaningfully divergent from our expectations.

The second point explains about the YoY results. We have invested aggressively in R&D expenses, which have increased from last year. Regarding revenue, we booked one-time fees from Roche and BDSI in the previous fiscal year. In addition, royalties were impacted by the foreign exchange rates. As a result, we posted a significant decline in revenue and profits YoY.

As for foreign exchange rates, the yen slightly appreciated against the US dollar and depreciated against the British pound and the euro.

Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Revenue	318.1	**224.4**	**70.5**	254.8	**(11.9)**	**(30.3)**
Cost of sales	17.3 55.1	16.0 **35.9**	**65.3**	16.0 40.7	**(11.7)**	**(4.8)**
Gross profit	263.0	**188.5**	**71.7**	214.0	**(11.9)**	**(25.6)**
Selling general & administrative expenses	31.5 100.2	30.6 **68.6**	**68.5**	28.7 73.1	**(6.1)**	**(4.5)**
R&D expenses	16.4 52.0	17.5 **39.2**	**75.4**	13.7 34.9	**12.6**	**4.4**
Other income	25.5	**23.3**	**91.4**	3.0	**687.4**	**20.4**
Other expenses	3.1	**1.7**	**55.8**	2.4	**(27.3)**	**(0.6)**
Operating profit**	41.9 133.2	45.5 **102.2**	**76.7**	41.9 106.7	**(4.2)**	**(4.5)**
Core operating profit	34.1 108.5	35.6 **80.0**	**73.7**	41.0 104.4	**(23.4)**	**(24.5)**
Finance income	28.3	**15.9**	**56.1**	18.5	**(14.0)**	**(2.6)**
Finance costs	1.9	**1.3**	**66.0**	1.5	**(18.0)**	**(0.3)**
Profit before tax	50.2 159.6	52.1 **116.8**	**73.2**	48.5 123.6	**(5.5)**	**(6.8)**
Profit attributable to owners of parent	119.7	**86.1**	**71.9**	94.3	**(8.7)**	**(8.2)**

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* Converted from JGAAP to IFRS
** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

Next, I will go over the statement of profit and loss on page 6.

As I stated earlier, revenue was JPY224.4 billion. The cost of sales was JPY35.9 billion, reflecting 65.3% of the full-year forecast. Netting the two figures, the gross profit was JPY188.5 billion, indicating 71.7% of the full-year forecast.

On the other hand, SG&A expenses were JPY68.6 billion, which is 68.5% of the full-year forecast. Of course, the expenses have fallen below the plan, partly due to being linked to revenue, but they also reflect how activities have been slightly more sluggish than anticipated. As a result, the progress rate is as shown here.

R&D expenses were JPY39.2 billion, indicating a 75.4% progress rate. This is the result of R&D expenses related to COVID-19 and the steady progress made in each project.

Other income came to JPY23.3 billion due to the recording of around JPY22.9 billion in the exchange gain of our Shionogi Shibuya building, which has been recorded as planned.

Netting the above, operating profit amounted to JPY102.2 billion, indicating 76.7% of the full-year forecast. Core operating profit was JPY80.0 billion, achieving 73.7% of the full-year forecast.

On the other hand, finance income came to JPY15.9 billion, which is 56.1% of the full-year forecast, mainly due to dividends from ViiV falling slightly short of our expectations. This figure may fluctuate on a quarterly basis, but we expect it to be in line with the plan on a full-year basis.

Netting the above, profit before tax was JPY116.8 billion and profit attributable to owners of parent was JPY86.1 billion.

Revenue by Segment

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Domestic Prescription drugs	115.3	**71.8**	**62.3**	80.3	**(10.5)**	**(8.4)**
Overseas subsidiaries/export	24.0	**17.5**	**72.7**	24.0	**(27.2)**	**(6.5)**
Shionogi Inc.	6.2	**5.4**	**87.0**	8.5	**(36.5)**	**(3.1)**
C&O	10.5	**6.9**	**66.1**	10.2	**(32.0)**	**(3.3)**
Contract manufacturing	17.1	**10.3**	**60.1**	12.0	**(14.3)**	**(1.7)**
OTC and quasi-drug	11.9	**8.8**	**74.2**	7.0	**25.5**	**1.8**
Royalty income	148.3	**114.8**	**77.4**	129.8	**(11.5)**	**(14.9)**
HIV franchise	126.3	**95.1**	**75.3**	97.8	**(2.8)**	**(2.7)**
Crestor®	16.9	**16.6**	**98.3**	16.7	**(0.9)**	**(0.2)**
Others	5.2	**3.2**	**61.9**	15.3	**(79.1)**	**(12.1)**
Others	1.5	**1.2**	**80.0**	1.7	**(29.1)**	**(0.5)**
Total	**318.1**	**224.4**	**70.5**	**254.8**	**(11.9)**	**(30.3)**

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* Converted from JGAAP to IFRS

Please move on to page 7. Here is the revenue breakdown.

Out of total revenue of JPY224.4 billion, domestic prescription drugs posted JPY71.8 billion or 62.3% of the target, chiefly due to the impact explained at the outset. I will explain the breakdown on a later page.

For Overseas, Shionogi Inc. posted JPY5.4 billion or 87.0% of the target. The higher-than-standard progress rate mainly reflects the above-standard progress in Cefiderocol. On the other hand, C&O posted the result shown here due to the delayed progress in rabeprazole.

As for contract manufacturing, we mainly see a slight delay related to Xofluza exports. OTC and Quasi-drug posted JPY8.8 billion or 74.2% of the target, which is the result of favorable trends in infectious disease-related products.

We consider the progress in royalty income to be roughly in line with the plan. I will talk about the YoY results altogether later.

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Cymbalta®	28.2	**20.5**	**72.7**	20.2	**1.5**	**0.3**
Intuniv®	15.9	**9.6**	**60.4**	7.1	**35.5**	**2.5**
Vyvanse®**	0.7	**0.2**	**26.2**	0.0	-**	-**
Infectious disease drugs	22.8	**7.6**	**33.3**	12.8	**(40.7)**	**(5.2)**
Influenza franchise	12.9	**0.2**	**1.9**	2.1	**(88.2)**	**(1.8)**
OxyContin® franchise	5.4	**4.1**	**75.1**	4.7	**(13.4)**	**(0.6)**
Symproic®	2.7	**1.7**	**61.9**	1.5	**7.6**	**0.1**
Actair®	0.3	**0.2**	**71.1**	0.2	**30.5**	**0.1**
Mulpleta®	0.1	**0.1**	**67.9**	0.1	**(25.0)**	**(0.0)**
Pirespa®	4.8	**4.0**	**83.1**	5.0	**(19.0)**	**(0.9)**
Others	34.4	**23.9**	**69.6**	28.7	**(16.6)**	**(4.8)**
Crestor®	7.8	**5.1**	**65.2**	6.6	**(22.5)**	**(1.5)**
Irbetan® franchise	3.6	**2.6**	**70.7**	3.2	**(20.7)**	**(0.7)**
Prescription drugs	**115.3**	**71.8**	**62.3**	**80.3**	**(10.5)**	**(8.4)**

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc®Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Seftem®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole
- ISODINE®

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Influenza franchise

* Converted from JGAAP to IFRS

** Launched in Dec. 2019

On page 8, I would like to look at the breakdown of prescription drug revenue in Japan.

Total revenue of domestic prescription drugs came to JPY71.8 billion or 62.3% of the target. As I stated at the outset, revenue from infectious disease drugs has diverged considerably from the forecast at JPY7.6 billion or 33.3% of the target. This is, of course, mainly due to the impact of sharply lower-than-expected revenue from the influenza family of drugs, such as Xofluza.

Other than that, Cymbalta and Intuniv revenue was slightly below standard. We believe there has been at least some impact from people refraining from visiting hospitals.

For Others, the progress rate was below standard at 69.6%. This was primarily attributable to the content of long-term listings. For example, the revenue of cough suppressants like Medicon has declined significantly compared to normal years. These factors are appearing in the aggregate result.

Year-on-Year Comparison

- **Revenue (-30.3 B yen [-11.9%]** reference: -15.2 B yen at 1H **)**
  - **Domestic Prescription drugs (-8.4 B yen [-10.5%])**
    - > Increase: Sales of Intuniv®
    - > Decrease: Sales of Infectious disease drugs and impact of price revision (long-listed products in "Infectious disease drugs" and "Others")
  - **Overseas subsidiaries/export (-6.5 B yen [-27.2%])**
    - > Increase: US: Steady progress of cefiderocol
    - > Decrease: US: One-time payment received from BDSI* for Symproic® in FY2019 (one-time income of 1Q)
      China: sales of rabeprazole in the hospital market
  - **Contract manufacturing (-1.7 B yen [-14.3%])**
    - > Increase: Recording of contract manufacturing revenue of Nagase Medicals
    - > Decrease: Temporal reduction of dolutegravir API supply, due to manufacturing process improvements (already included in the original forecast)
      Export of Xofluza® based on this season's influenza epidemic situation
  - **OTC and quasi-drug (1.8 B yen [25.5%])**
    - > Increase: Infectious disease-related products
  - **Royalty revenue (-14.9 B yen [-11.5%])**
    - > Decrease: One-time payment received from Roche for Xofluza® in FY2019 (one-time income of 3Q)
      Exchange rate impact on royalty income from HIV franchise (£/$, £/¥)

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* BioDelivery Sciences International, Inc.

Next, on page 9 and 10, I would like to explain a little about the YoY comparison.

Revenue declined by JPY30.3 billion or 11.9%. domestic prescription drugs revenue fell by JPY8.4 billion or 10.5%, mainly due to the decrease in infectious disease drugs, as stated earlier, and a decline stemming from drug price revisions.

Overseas revenue fell by JPY6.5 billion or 27.2%. The decline was mainly attributable to the one-time fee from BDSI recorded last year and a slightly sluggish rabeprazole sales, despite steady progress in Fetroja.

Contract manufacturing revenue fell by JPY1.7 billion, down 14.3%. The biggest reason behind the decline was a reduction in influenza-related Xofluza exports.

OTC and Quasi-drug revenue increased by 25.5% due to strong sales of infectious disease-related products, as stated earlier.

Royalty revenue fell by JPY14.9 billion or 11.5%. The greatest factor behind the decline was the one-time fee from Roche that was recorded last year. In addition, there was a slight impact from the foreign currency exchange rate at our HIV franchise.

Year-on-Year Comparison

- **Cost of sales (-4.8 B yen [-11.7%]** reference: -4.8 B yen at 1H**)**
  - Increase: Sales of OTC and quasi-drugs and addition of Nagase Medicals
  - Decrease: Sales of medical drugs (as the one-time income was royalty income, there is no cost reduction effect due to the decrease in income in FY2019)
- **Selling general & administrative expenses (-4.5 B yen [-6.1%]** reference: -3.5 B yen at 1H**)**
  - Increase: Initiating business of Ping An JV and investing in Nagase Medicals
  - Decrease: Cost due to decreasing opportunities to visit medical institutions
- **R&D expenses (4.4 B yen [12.6%]** reference: 1.5 B yen at 1H**)**
  - Increase: Accelerating progress of COVID-19 related projects, and 8 core projects including S-600918 and S-005151
- **Other income (20.4 B yen [687.4%]** reference: 0.0 B yen at 1H**)**
  - Increase: Gain on exchange of Shionogi Shibuya Building (one-time income of 3Q)

Moving to page 10, the cost of sales fell by JPY4.8 billion or 11.7%, corresponding to the decrease in sales.

SG&A expenses fell by JPY4.5 billion or 6.1%, chiefly due to the slight shortfall in activities as stated earlier.

R&D expenses increased by JPY4.4 billion or 12.6%, owing to R&D related to COVID-19 and steady progress in major projects.

Other income was as I explained earlier.

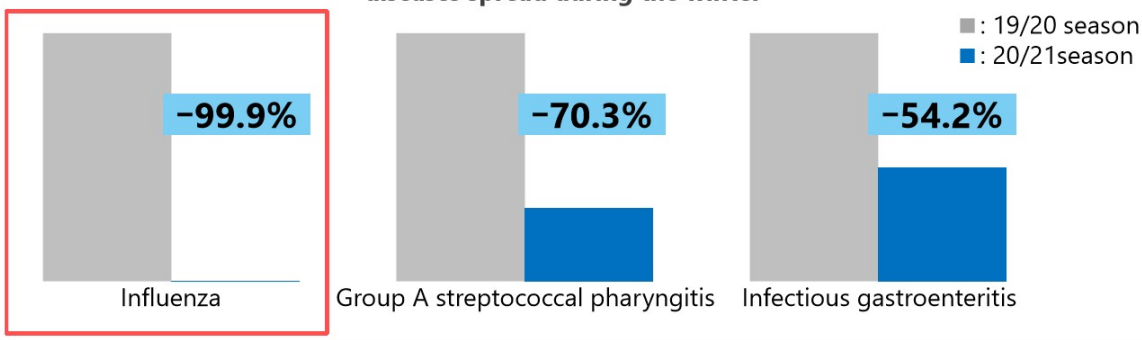
This concludes the explanation of results. From page 11, I will briefly go over the full-year financial forecast.

Impact of COVID-19 on Infectious disease drug market

- Many infectious diseases dropped dramatically as people took steps to prevent COVID-19 infection
- The impact of a prolonged pandemic on the infectious disease drug market should continue to be carefully estimated.

Downward revisions to forecasts for influenza-related products, considering the latest epidemic situation

Rate of decline from previous season in the number of patients with the main infectious diseases spread during the winter



Prepared from Infectious Diseases Weekly Report Japan: Cumulative number of domestic fixed-point reports (Oct.-Dec.)

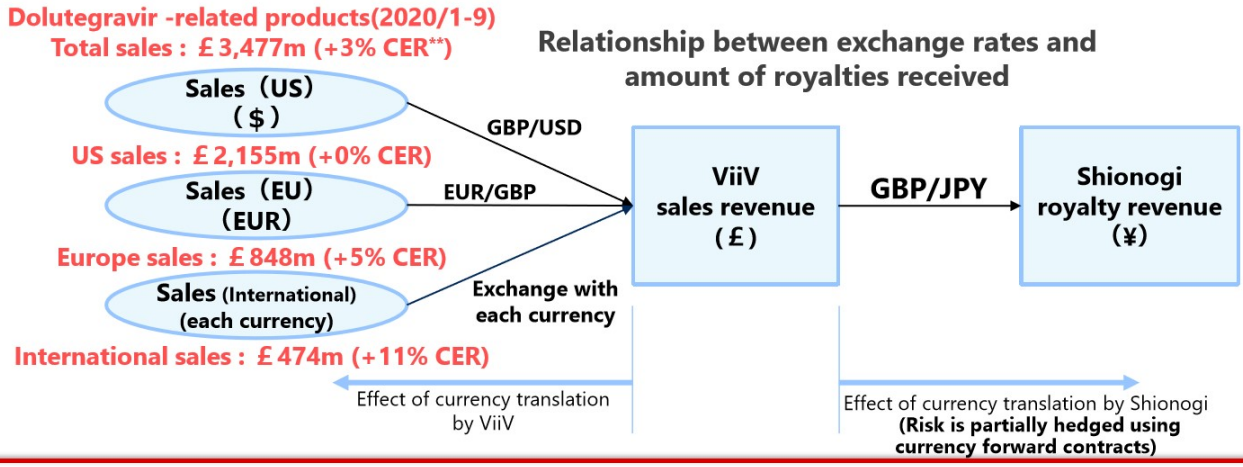
First, please see page 12. As I touched on earlier, the influenza-related drugs market was heavily impacted by the COVID-19 pandemic.

Due to the enforcement of prevention measures against COVID-19 infection, people's behaviors have changed significantly. As shown in the graph on the bottom, there has been almost no spread of influenza, and there has been a sharp drop in other infectious diseases, too. This illustrates the current state of the infectious disease drugs market.

Impact of Exchange fluctuation

- Sales of HIV products in the U.S. are recognized by ViiV after being translated from dollars into pounds
- In 3Q, the pound appreciated substantially against the dollar, so the amount of royalty revenue received declined
  - **Sales by ViiV remained strong as expected**

Downward revision of HIV franchise* royalty revenue forecast



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* HIV franchise: Tivicay®、Triumeq®、Juluca®、Dovato®

** Constant exchange rate growth

On page 13, we have described the impact of exchange rate fluctuations. Dolutegravir-related sales results up to September have already been announced. We understand that steady progress is mostly being made on a volume basis.

However, in terms of the foreign exchange rates, ViiV revenue was impacted by the GBP appreciation and USD depreciation particularly for the GBP/USD pair. Due to this stronger GBP and weaker USD, the GBP-denominated revenue, which is the basis on which royalty revenue is calculated, was slightly affected.

Of course, we have the GBP/JPY pair hedged with forward contracts. But this GBP/USD figure is converted as part of ViiV's earnings results. Hence, we have been impacted.

Revision of earnings forecast
Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020 Full year forecast				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Cymbalta®	28.6	28.2	**27.4**	**(0.7)**	26.2	**4.7**	**1.2**
Intuniv®	16.7	15.9	**14.0**	**(1.9)**	10.6	**31.2**	**3.3**
Vyvanse®* **	0.8	0.7	**0.5**	**(0.2)**	0.0	**–*** **	**0.4**
Infectious disease drugs	26.5	22.8	**10.6**	**(12.2)**	16.0	**(33.6)**	**(5.4)**
Influenza franchise	13.3	12.9	**0.7**	**(12.2)**	2.4	**(69.6)**	**(1.7)**
OxyContin® franchise	5.6	5.4	**5.5**	**0.1**	5.8	**(5.2)**	**(0.3)**
Symproic®	2.9	2.7	**2.3**	**(0.4)**	2.1	**8.7**	**0.2**
Actair®	0.3	0.3	**0.3**	**–**	0.3	**23.2**	**0.1**
Mulpleta®	0.1	0.1	**0.1**	**–**	0.1	**(9.9)**	**(0.0)**
Pirespa®	4.9	4.8	**5.2**	**0.4**	6.8	**(22.5)**	**(1.5)**
Others	37.5	34.4	**32.3**	**(2.0)**	38.3	**(15.5)**	**(5.9)**
Crestor®	8.3	7.8	**6.9**	**(0.9)**	8.6	**(20.1)**	**(1.7)**
Irbetan® franchise	3.7	3.6	**3.4**	**(0.2)**	4.2	**(19.4)**	**(0.8)**
Prescription drugs	**123.9**	**115.3**	**98.3**	**(16.9)**	**106.3**	**(7.5)**	**(7.9)**

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc®Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Seftem®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole
- ISODINE®

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Influenza franchise

* Comparison to revised forecast (2/1)
** Converted from JGAAP to IFRS
*** Launched in Dec. 2019

On page 14, we have described the numbers for the revised earnings forecast of prescription drugs in Japan.

We forecast total revenue of JPY98.3 billion, a revision of JPY16.9 billion.

As I stated earlier, the revision is mainly due to JPY12.2 billion attributable to infectious disease drugs and numbers for the influenza-family drugs. We have also made slight revisions for Cymbalta and Intuniv, considering the most recent progress. The same applies to other items.

Revision of earnings forecast
Sales by Segment

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Domestic Prescription drugs	123.9	115.3	**98.3**	**(16.9)**	106.3	**(7.5)**	**(7.9)**
Overseas subsidiaries/export	24.0	24.0	**24.5**	**0.5**	30.8	**(20.3)**	**(6.3)**
Shionogi Inc.	5.1	6.2	**7.0**	**0.8**	10.1	**(31.1)**	**(3.2)**
C&O	11.9	10.5	**10.1**	**(0.4)**	13.1	**(23.1)**	**(3.0)**
Contract manufacturing	15.4	17.1	**19.0**	**1.9**	17.6	**7.8**	**1.4**
OTC and quasi-drug	10.4	11.9	**11.9**	**–**	9.7	**22.3**	**2.2**
Royalty income	148.3	148.3	**146.2**	**(2.1)**	166.9	**(12.4)**	**(20.7)**
HIV franchise	126.3	126.3	**124.3**	**(2.0)**	128.1	**(3.0)**	**(3.8)**
Crestor®	16.9	16.9	**16.9**	**–**	22.3	**(24.2)**	**(5.4)**
Others	5.2	5.2	**5.0**	**(0.2)**	16.5	**(69.8)**	**(11.5)**
Others	1.3	1.5	**1.5**	**(0.0)**	2.2	**(28.9)**	**(0.6)**
Total	**323.5**	**318.1**	**301.4**	**(16.7)**	**333.4**	**(9.6)**	**(32.0)**

The revised forecast includes Ping An-Shionogi's revenue forecast. The impact will be minor due to short accounting recognition period.

SHIONOGI * Comparison to revised forecast (2/1) ** Converted from JGAAP to IFRS

Next, on page 15, I will report on the revision to revenue other than prescription drugs.

We forecast total revenue of JPY301.4 billion, a revision of JPY16.7 billion.

In addition to a revision of JPY16.9 billion in domestic prescription drugs, we slightly revised up our forecast for overseas revenue due to the steady progress in Fetroja, as stated earlier.

We also upwardly revised the forecast for contract manufacturing revenue in consideration of expected Xofluza exports during the January to March period.

As for royalty income, we have downwardly revised our forecast due to some exchange rate factors explained earlier. In total, the revision amounts to JPY16.7 billion, for a full-year revenue forecast of JPY301.4 billion.

Revision of earnings forecast
Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Revenue	323.5	318.1	**301.4**	**(16.7)**	333.4	**(9.6)**	**(32.0)**
Cost of sales	17.2 55.7	17.3 55.1	18.1 **54.5**	**(0.6)**	17.0 56.8	**(4.0)**	**(2.3)**
Gross profit	267.8	263.0	**246.9**	**(16.1)**	276.6	**(10.7)**	**(29.7)**
Selling general & administrative expenses	32.1 103.7	31.5 100.2	31.3 **94.4**	**(5.8)**	29.5 98.4	**(4.0)**	**(4.0)**
R&D expenses	15.5 50.2	16.4 52.0	17.3 **52.0**	**–**	14.4 47.9	**8.4**	**4.1**
Other income	0.5	25.5	**25.5**	**–**	4.3	**494.2**	**21.2**
Other expenses	4.0	3.1	**3.1**	**–**	4.0	**(21.5)**	**(0.9)**
Operating profit	34.1 110.3	41.9 133.2	40.8 **122.9**	**(10.3)**	39.2 130.6	**(5.9)**	**(7.7)**
Core operating profit	34.1 110.3	34.1 108.5	32.4 **97.7**	**(10.8)**	38.2 127.4	**(23.3)**	**(29.6)**
Finance income	27.5	28.3	**28.3**	**-**	30.5	**(7.2)**	**(2.2)**
Finance costs	1.6	1.9	**1.9**	**-**	2.6	**(27.2)**	**(0.7)**
Profit before tax	42.1 136.3	50.2 159.6	49.5 **149.3**	**(10.3)**	47.5 158.5	**(5.8)**	**(9.2)**
Profit attributable to owners of parent	103.6	119.7	**113.7**	**(6.0)**	122.2	**(7.0)**	**(8.5)**

SHIONOGI

The revised forecast includes Ping An-Shionogi's revenue forecast.
The impact will be minor due to short accounting recognition period.

* Comparison to revised forecast (2/1)
** Converted from JGAAP to IFRS

On page 16, we have described the revisions to the full-year earnings forecast in the profit and loss statement.

We expect revenue of JPY301.4 billion, a revision of JPY16.7 billion. Correspondingly, we revised down the cost of sales by JPY0.6 billion. As a result, we have revised the gross profit forecast by JPY16.1 billion.

We expect SG&A expenses of JPY94.4 billion, a revision of JPY5.8 billion. The revision reflects a careful examination of expenses and the results of cost control.

Based on the above, we expect operating profit of JPY122.9 billion, a revision of JPY10.3 billion. Similarly, we have revised core operating profit by JPY10.8 billion and profit before tax by JPY10.3 billion. We have revised profit attributable to owners of parent by JPY6.0 billion.

Revision of earnings forecast (Announced on February 1, 2021)

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Revenue	323.5	318.1	**301.4**	**(16.7)**	333.4	**(9.6)**	**(32.0)**
Operating profit	110.3	133.2	**122.9**	**(10.3)**	130.6	**(5.9)**	**(7.7)**
Core operating profit* **	110.3	108.5	**97.7**	**(10.8)**	127.4	**(23.3)**	**(29.6)**
Profit before tax	136.3	159.6	**149.3**	**(10.3)**	158.5	**(5.8)**	**(9.2)**
Profit attributable to owners of parent	103.6	119.7	**113.7**	**(6.0)**	122.2	**(7.0)**	**(8.5)**

Exchange Rate (average)	FY2020 forecast (May.11)	FY2020 forecast (revise on Oct.30)	FY2020 forecast (revise on Feb.1)	FY2020 Apr.-Dec. results
USD ($) –JPY(¥)	107.00	107.00	**105.50**	**106.11**
GBP (£) –JPY(¥)	130.00	135.00	**137.50**	**136.29**
EUR (€) –JPY(¥)	120.00	120.00	**123.00**	**122.45**

Forecast excluding a gain on exchange of Shionogi Shibuya Building (22.9 B yen) is in Appendix p.27

SHIONOGI

* Comparison to revised forecast (2/1) ** Converted from JGAAP to IFRS *** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

On page 17, we have indicated a summary chart of the forecast revisions.

We forecast revenue of JPY301.4 billion, operating profit of JPY122.9 billion, core operating profit of JPY97.7 billion, profit before tax of JPY149.3 billion, and profit attributable to owners of Parent of JPY113.7 billion. We will do our best to deliver FY2020 results exceeding these numbers. We ask for your continued support.

That is all for my explanation of the numbers.

Core 8 Projects Update

	Pipeline	Indication	Status
Infectious disease	**S-540956**	HIV infection, cancer	Non-clinical studies are progressing to support initiation of Phase I study in FY2020 4Q
Psycho-neurological diseases	**S-600918**	① Refractory chronic cough ② sleep apnea syndrome	① Phase 2b: **completed enrollment** ⇒topline results are anticipated in FY2021 1Q ② Phase 2a in progress (Japan)⇒topline results are anticipated in FY2021 1Q
	S-637880	Neuropathic low back pain	Phase 2a in progress (Japan)
	zuranolone [S-812217]	Depression	Phase 2 in progress (Japan)
	BPN14770	① Alzheimer's disease ② Fragile X Syndrome	① Phase 1 in progress (Japan) ② Preparations for Phase 3
	S-874713	Psycho-neurological diseases	Non-clinical studies are progressing to support initiation of Phase I study in FY2020 4Q
New growth areas	**S-531011**	Solid tumor	Non-clinical studies are progressing to support initiation of Phase I study in FY2021 2Q
	redasemtide [S-005151]	① Epidermolysis bullosa ② Acute stroke ③ Osteoarthritis ④ Chronic liver disease	① Preparing for application ② Phase 2 in progress (Japan) ③ Phase 2 in progress (Japan) (Investigator initiated clinical trial) ④ Phase 2 in progress (Japan) (Investigator initiated clinical trial)

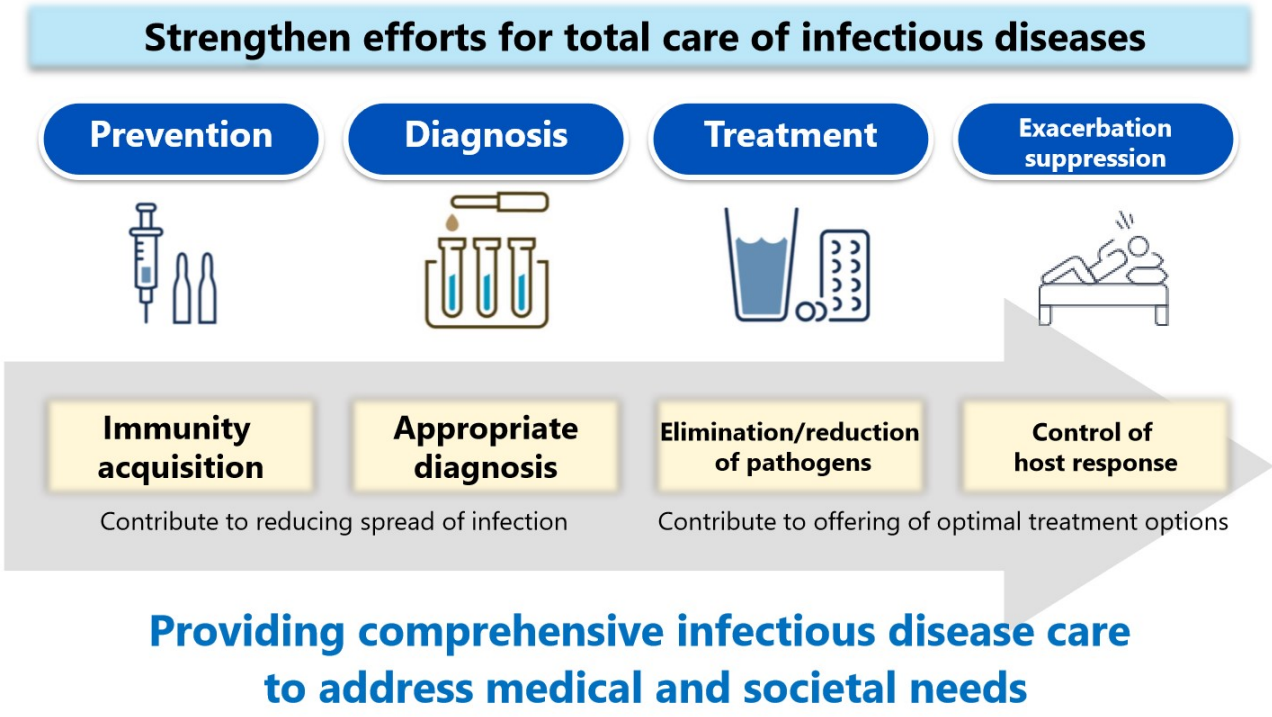
Steady progress of R&D activity centered on core 8 projects*

Hanasaki: This is Hanasaki. Next, I will explain our actions for future growth. On page 19, we have summarized an update on the core 8 projects.

R&D activities have made steady project centering on these 8 projects. In particular, the topic for the third quarter is that we have completed Phase 2b enrollment of S-600918 indication for refractory chronic cough. We plan to obtain topline results during the first quarter of FY2021, along with its indication for sleep apnea syndrome.

Regarding S-637880, Phase 2a is in progress in Japan. As for redasemtide's indication for osteoarthritis and chronic liver disease written on the very bottom, the update is that clinical trials have been initiated by investigators.

As a Leading Company in the Infectious Disease Field



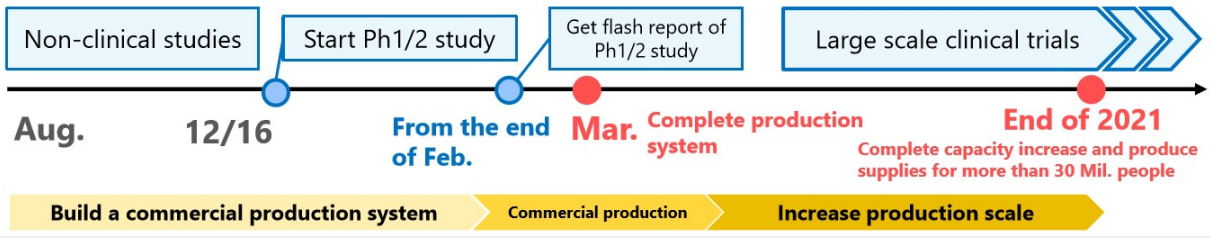
Continuing onto page 20, we are strengthening efforts for total care of infectious diseases, including prevention, diagnosis, treatment, and exacerbation suppression, as a leading company in the infectious disease field.

In particular, I would like to give an update on our efforts to fight COVID-19.

Our Efforts to Fight COVID-19

Development of Prophylactic Vaccine (S-268019)

- **Developing a recombinant protein vaccine** based on established technology
- Selection of the antigen and the adjuvant
  - Confirmed efficacy of vaccination in preventing exacerbation in an animal study
- Ph1/2 clinical trial* started in December 2020
  - No major safety concerns so far
  - In discussion with regulatory authorities to start global Ph3 trials later this year, considering further plans
- **Complete production system** in collaboration with UNIGEN (antigen production) and API (formulated product manufacturing) **within FY2020**



SHIONOGI

* Randomized double-blind placebo controlled trial involving 200 or more Japanese adults
In two parts of clinical trials, Ph1 for confirmation of safety and tolerability, and Ph2 for the second to investigate the optimal dose
The vaccine was administered two times with a gap of three weeks between inoculations, and safety, tolerability, and immunogenicity were assessed for a period of one year post-inoculation

On page 21, I will first explain the development status of the prophylactic vaccine S-268019.

We selected an antigen for the recombinant protein vaccine using BEVS technology developed by UMN and an adjuvant. Phase 1/2 clinical trials have started from December 16.

Details of these trials are described at the bottom. The trial targets more than 200 Japanese adult subjects. In the first phase, safety and tolerability are confirmed. And, in the second phase, the optimal dose is examined. The study has begun on the safety, tolerability, and immunogenicity of two doses of this vaccine at three-week intervals, and a follow-up of this vaccine will be done for one year post-inoculation.

At this point, there are no major safety concerns. We will continue to consult with the authorities toward starting the global Phase 3 trial within the year and aiming to accelerate the schedule.

On the other hand, regarding production activities, we plan to establish a production system by the end of FY2020, in collaboration with UNIGEN and API.

As for the schedule, we plan to obtain preliminary data on the start of Phase 1 and Phase 2 trials that will be available on a rolling basis from the end of February.

Regarding production, we will complete the construction of a supply system in March. We aim to build a system to increase production so that we can supply doses for 30 million people by the end of 2021.

Our Efforts to Fight COVID-19

Business alliance to control exacerbation

- **Conclusion of basic agreement with BioAge aiming to suppress the exacerbation of infectious diseases with S-555739**
  - ✓ Shionogi granted BioAge the exclusive US and European rights to develop and commercialize S-555739 for COVID-19 treatment
  - ✓ Shionogi granted BioAge the exclusive rights to negotiate a license for further indications
  - – **BioAge Labs, Inc.**
    - > Clinical-stage biotechnology company that develops drugs to treat aging and aging-related diseases
    - > Building a biology platform to map out the key molecular pathways that impact healthy human aging, based on proprietary human aging cohorts that have blood samples collected up to 45 years ago with participant-omics data
  - – **S-555739（BioAge code: BGE-175）**
    - > Prostaglandin D2 DP1 receptor antagonist which conducted Ph3 study with allergic rhinitis as an indication*
    - > Improvement of allergic symptoms in animal model and high affinity for DP1 receptor had confirmed in non-clinical studies
    - > Proven good tolerability and safety in clinical trials**

Discovery of Therapeutic Drugs

- Abandoned the initial goal of starting clinical study within FY2020 as more efficacy and safety studies are needed
- **We are continuing our drug discovery efforts not only for SARS-CoV-2 but also for other corona viruses to prepare for the potential for future corona virus pandemics**
- Producing more effective and safer drug by taking advantage of various modalities

Offering Test/Diagnosis Kit***

- Reviewing the release target date of the initial product and formulating a new development plan
- **In parallel, accelerating studies for early provision of kits that enable easier and quicker diagnosis of multiple samples**

SHIONOGI

* Development for this indication was halted in November 2016
** See Appendix p.29
*** R&D involving the SATIC method conducted jointly with Nihon University, Gunma University, and Tokyo Medical University

Next, please go to page 22.

This time, as a business alliance aimed at suppressing the exacerbation of infectious diseases, we formed the alliance with BioAge for S-555739, which is a prostaglandin D $_2$DP1 receptor antagonist previously developed for allergic rhinitis.

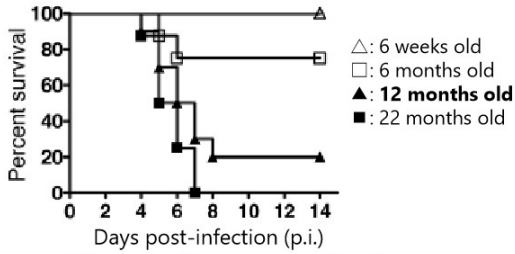
The business alliance will grant BioAge exclusive development and marketing rights in the US and Europe for the treatment of COVID-19, and it will also grant exclusive rights to negotiate a license for further indications.

Here, we have written an explanation about BioAge. In particular, BioAge has built a biology platform to map out the key molecular pathways that impact healthy human aging, based on proprietary human aging cohorts that have blood samples collected up to 45 years ago with AI-driven omics date. By doing so, it has identified targets related to PGD_2. And it has made progress in the drug repositioning of S-555739.

Non-clinical data have confirmed the high affinity and selectivity of this compound for DP1 receptor. In clinical trials, we have already obtained data that proves the tolerability and safety of the compound.

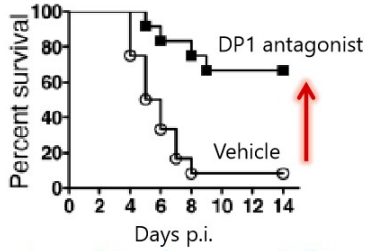
Mortality Reduction by Inhibition of PGD_2 DP1 in Elderly Mice Infected with SARS-CoV

Comparison of mortality rates of various aged mice infected with SARS-CoV*



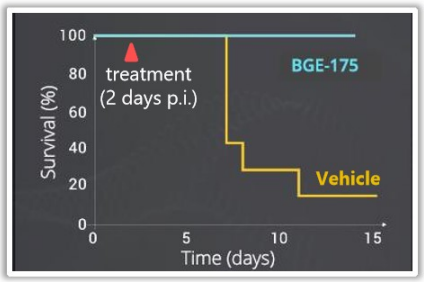
Increase in mortality rates with aging

Mortality suppression through DP1 antagonist in **12 months old mice**



DP1 antagonist reduces mortality rate in elderly mice

BGE-175 reduced mortality rate of 8 months old mice infected with SARS-CoV (conducted by BioAge)



J. Clin. Invest., 2011;121(12):4921-4930

- DP1 antagonist promotes the acquisition of immunity in elderly mice
  - → **Possibility of suppressing exacerbation of COVID-19 and other infectious diseases**
  - → **BioAge plans to start Phase 2 trial for COVID-19 from Feb. 2021**

SHIONOGI * A strain adapted from the SARS coronavirus strain that was prevalent in 2002 for use in animal studies 23

On page 23, we explain the specific effect of suppressing death in elderly mice regarding this point.

The upper part shows the data quoted from a research paper conducted at the University of Iowa published in 2011.

On the left side, we show a strain adapted from the SARS-CoV strain that was prevalent in 2002 for use in animal studies, which was administered to elderly mice from six weeks to 22 months of age. When infecting the mice with this strain, no deaths were seen at six weeks of age. However, there was data that the mortality rate and severity rate worsen with aging, such as six months old, 12 months old, and 22 months old.

The data shows that when an existing DP1 antagonist is pre-administered to 12-month-old mice, the lethal effect of the strain is suppressed.

This paper on the study at the University of Iowa produces data that the level of PGD_2 in the lung tissue increases with this age-related infection. Furthermore, it shows that this high level of PGD_2 inhibits the induction of specific T cells against pathogens. It is known that this leads to the suppressive effect of DP1 antagonists on the aggravation of such infections.

Based on this data, BioAge has confirmed the lethal inhibitory effect of this drug, S-555739, in the same SARS-CoV infected mice at eight months old, as shown in the lower left. Data have shown that administration of this drug two days before injecting the virus improves the mortality rate of mice.

Based on such data, it is expected that there is a possibility of severe suppression of DP1 antagonists, COVID-19 and other infectious diseases. Hence, BioAge is scheduled to start a Phase 2 study of the drug's efficacy on COVID-19 starting in February.

This concludes the explanation about our business alliance aimed at controlling exacerbation. I would like to return to page 22.

The next topic is the creation of a therapeutic drug for COVID-19. Regarding this point, we abandoned the start of clinical trials within the fiscal year because it is necessary to further verify the efficacy and safety as previously stated in our earnings announcement.

We are looking ahead to the next pandemic and the creation of therapeutic drugs that will also be effective against coronavirus other than SAR-CoV-2. Specifically, we are considering new drugs that are more effective and safer than existing drugs, including various drug discovery modalities other than small molecule pharma.

On the other hand, regarding the rapid diagnosis kits, this is the status of the SATIC method jointly conducted with three universities. We aimed to provide early products by the end of last year, but we are reviewing this goal and currently formulating a new development plan.

Since it is necessary to partially improve the reaction reagents, we are currently conducting studies to quickly deliver an improved kit that enables simpler and quicker diagnosis of multiple samples by examining each reaction process or scaling up.

This concludes our update on our efforts related to COVID-19.

Progress of cefiderocol

A new model to obtain stable return*

- United Kingdom
  - **Adopted for subscription-type reimbursement model** (12/18)
    - > A system where the government pays the company a fixed amount of compensation regardless of the amount of antimicrobial drugs prescribed, and the government can ensure availability of the antimicrobial drugs needed
    - > Subscription payment contract period is scheduled to start in April 2022
- Sweden
  - **Started supply as a delinked incentive model target** (1/1)
    - > A system where payment for a minimum amount is guaranteed, and if the amount supplied exceeds the minimum, revenue for that is also earned

Expand sales to EU

- Germany
  - Available from 1/15
    - > New health reimbursement evaluation method will be introduced
- Preparing for release in France, Italy and Spain

* See Appendix p.30

Next, on page 24, I will report on the progress of cefiderocol.

As Hosogai announced earlier, steady progress is being made in the US, especially in light of the expanded indications for hospital-acquired pneumonia. We are also expanding the drug's adoption in Europe.

We are developing a new earnings model that generates stable revenues while promoting proper use. In this context, the United Kingdom adopted a subscription-type reimbursement model in December.

This system allows the government to receive the required amount of antibacterial drugs in exchange for paying a fixed compensation to the company regardless of the amount of antibacterial drugs prescribed. The subscription payment contract period is scheduled to start in April 2022 after the medical technology evaluation by NICE is conducted in 2021.

In January, we started supply as a delinked incentive model target. This is a system where payment for a minimum amount is guaranteed, and if the amount supplied exceeds the minimum, revenue for that is also earned.

Sales have expanded to Germany from January 15. We are in the stage of preparing to expand sales in France, Italy, and Spain.

Progress of HIV Franchise by ViiV

- 「Growth through 2 Drug Regimens (DRs)」,「Prevention Market transformation」-

Strong momentum and development progress on 2DRs

Juluca (DTG/RPV*1) Dovato (DTG/3TC*2) CABENUVA (CAB/RPV*3)

- **Juluca and Dovato drive growth in HIV franchise**
  - Increase notable especially in US DTG NBRx*4 share
- **Dovato**
  - Increased share in switch market（U.S. Approved Aug. 2020: switch patients）
  - Long-term safety and efficacy results from TANGO study 96w, GEMINI study 144w
- **Cabotegravir**：Cabenuva（U.S., Canada）、Vocabria+Rekambys（Europe）
  - U.S. ,Canada, Europe Approved、**Scheduled for market launch in Feb. 2021**
  - New treatment can enable people living with HIV to reduce the days they receive treatment from **365 to 12** (U.S. ,Canada, Europe) or **6** per year (Europe)
  - Improvement of QOL:「Convenience」、「Medication Adherence」、「Reduce daily awareness of HIV」、「Privacy」
  - Efficacy and safety were confirmed in 5 years of continuous dosing
  - Strong patient preference:>97% of patients in pivotal ATLAS and FLAIR studies preferred LA regimen vs daily oral therapy

Prevention market transformation by cabotegravir

- **US submission expected mid-2021**
  - 66% more effective for men and 89% more effective for women than FTC/TDF*5 in preventing HIV infection
  - Received FDA Breakthrough Therapy Designation
  - $2bn market (>200k US PrEP patients) today, but up to 1.2m could benefit

SHIONOGI

*1 DTG/RPV: dolutegravir/ rilpivirine *2DTG/3TC: dolutegravir/lamivudine *3 CAB/RPV: cabotegravir/rilpivirine
*4 New-to-Brand Prescriptions *5 FTC/TDF: emtricitabine/tenofovir disoproxil fumarate

Finally, I will explain the progress of the HIV franchise by ViiV. I will explain from the perspectives of the two-drug regimen's growth and the preventive market's transformation.

Regarding the two-drug regimen, Juluca and Dovato are driving the growth of HIV. In particular, the number of newly adopted prescriptions is steadily increasing for these two drugs.

The efficacy and safety of Dovato have been confirmed by long-term data, especially based on results from TANGO and GEMINI studies. In August, the drug was indicated for switch patients in the US, and the market share among continuing patients is currently expanding.

On the other hand, cabotegravir, combined with rilpivirine, which is called Cabenuva in the US, is scheduled for market launch in the US in February. From the perspective of monthly injections, the number of days of treatment per year will be reduced from 365 to 12 days in the US, Canada, and Europe, and six days in Europe.

This is expected to improve patients' QOL from the perspective of convenience, medication adherence, reduction of daily awareness of HIV because it is not a tablet, and privacy. In addition, efficacy, safety, and tolerability have been confirmed in five years of continuous dosing.

Under these circumstances, the cabotegravir combination drug is expected to grow in the future as a new dosage form of the two-drug regimen.

Furthermore, in the prevention market for cabotegravir, the submission is scheduled to be filed in the US in the middle of 2021. The results of the HPTN study show that the preventive effect of cabotegravir is 66%

more effective for men and 89% more effective for women than Truvada. It is also designated as a breakthrough therapy by the FDA.

Currently, the market is worth $2 billion, and there are 200,000 patients in the US. According to a CDC report, this number could reach 1.2 million. We expect further growth of cabotegravir in this promising market.

In conclusion, the HIV franchise is expected to make steady progress in the prevention market for this two-drug regimen. Within that framework, we aim for further sustainable growth as a total healthcare company toward the realization of STS 2030.

This concludes the presentation of the third-quarter financial results.

Question & Answer

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

Operator: The first question will be from Mr. Yamaguchi of Citigroup. Please go ahead.

Yamaguchi: Thank you. I'd like to ask a specific question about the pipeline.

I believe there's a drug S-648414 for HIV. I thought the plan was to start Phase 2 trials during the current fiscal year and to receive Phase 2 result at a relatively early stage. How is this project progressing?

Sawada: We believe that there would be no point in developing this drug unless we are able to formulate not only an orally administered drug but also an injection long-acting type. We have halted the drug development for now in a sense because this long-acting injection is much more difficult to formulate.

Yamaguchi: Does that mean that the development will start as soon as this long-acting type is made, and there is a possibility that the plan will be pushed back if it cannot be made?

Sawada: Yes.

Yamaguchi: Okay. Also, in relation to the section on COVID-19, I would like to ask about S-555739.

I believe this is something that BioAge will decide after you out-license it, but isn't this originally an oral antiallergic agent?

Sawada: Yes, it is.

Yamaguchi: You said that it's for exacerbation suppression, but it's unclear which stage of patients will be administered with it. This disease has severe respiratory effects, so is it possible the drug will be converted to an injection? Or will it be administered orally to patients with mild symptoms to suppress the severity?

Sawada: At present, I believe it will be very interesting if the drug can be used to prevent the aggravation of the disease, given that the drug is safe enough to be administered from a relatively early stage.

Yamaguchi: Does that mean it will continue to be used orally?

Sawada: Yes. That is the current plan.

Yamaguchi: Okay. Lastly, I have a question about the COVID-19 vaccine. I believe SHIONOGI has been developing it steadily. In particular, it says here that you are preparing to start global Phase 3 trials for this vaccine within this year. Meanwhile, I believe there will be a trend for some time where foreign approved vaccines are tested on small groups in Japan and approved.

In global Phase 3 trials, foreign companies have conducted tests on about 40,000 people. Do you think it is possible that this scale of trial will be required for approval in Japan? Also, when applying for approval of this vaccine, how long do you think it will take until approval? I know there is a lot of uncertainty, but it would be great if you could tell me a little more about this.

Sawada: I believe that there is a possibility a Phase 3 trial of that scale would be required in consideration of demonstrating the efficacy. However, it is unclear when the trials can start because, even overseas, the

countries where clinical trials can be conducted are changing rapidly. If the trials must be conducted, then we hope to start as soon as possible, even a month earlier.

Yamaguchi: Does that mean that the vaccine is not in the stage of consulting with the authorities yet, given that it has not started the Phase 1 or Phase 2 trials yet? Will you only know after those trials?

Sawada: We have begun discussions with the authorities, but we have not yet finalized a complete development plan.

Yamaguchi: Okay. Separately, regarding the increase in production capacity, you plan on producing supplies for 30 million people by the end of the year, correct?

Sawada: Yes.

Yamaguchi: In that case, does it mean that you are currently in a position of needing to secure the production capacity, even though you are not sure whether the vaccine will be approved?

Sawada: Yes, I believe that is the same situation for other companies as well.

Yamaguchi: Okay. Thank you. That's all.

Operator: The next question will be from Mr. Ueda of Goldman Sachs Japan. Please go ahead.

Ueda: This is Ueda of Goldman Sachs Japan. For my first question, I would like to ask about a point in connection with the question asked just now.

When conducting the global Phase 3 trials in developing the COVID-19 vaccine, is it correct to understand that the proof of its efficacy will include comparisons with preceding foreign vaccines?

I assume that depending on the timing of when the trials will be done, the situation will change in terms of which variant strains are the most prevalent. How do you intend to design the clinical trial?

Sawada: In that case, I believe it will not only be PMDA, but presumably discussions will be required with overseas regulatory authorities. Currently, I believe the only ones who have announced they will conduct Phase 3 trials targeting positive-control studies are Sanofi and GSK Group.

Looking at the current distribution of vaccines, I believe it is still possible to conduct a placebo-controlled trial if we can enter the Phase 3 trials at a relatively early stage.

Of course, we are currently discussing with each regulatory authority based on a study of various data on how we could make other shortcuts. We hope to continue to have such discussions, but we are, of course, making preparations based on the possibility that a large scale Phase 3 trial may be required.

Although Sanofi and GSK have discussed a positive-control study, the current situation is one where governments are vying for vaccines. It is hard to think that manufacturers who have launched the vaccines on the market in advance have the extra supply they can provide to companies for clinical trials.

In that sense, we believe it won't be easy to start a clinical trial based on positive-control studies at an early stage. If they can adequately collect historical data, then it may be possible to conduct the trial based on that data. However, at this point, I believe that will be difficult.

Ueda: Okay. Thank you. Second, I would like to ask about the trends of the China business. Could you explain the progress in the joint venture with Ping An Group after you formed the joint venture?

Based on the forecast revisions this time, I get the impression that this JV's effects have not appeared in the results yet. When do you think we will be able to confirm the effects in the numbers? Also, I believe you had a plan to start to develop new products in China. Could you also inform us of the timing when we would be able to confirm those products?

Hanasaki: Regarding the joint venture with Ping An Group, the company was established on November 18, and a business license was granted. The originally planned capital injection started from the end of December.

As for the activities, we have announced a sales partnership with Good Doctor. Specifically, C&O product sales have started from the end of December.

Regarding development, preparations are being for IND and NDA of Cefiderocol. Although we are aiming for clinical exemption, we are simultaneously preparing the capacity to conduct clinical trials just in case.

Ueda: Thank you. In that case, do you think it's fair to say that in next fiscal year's guidance, you would be able to factor in some contributions from this business?

Hanasaki: Yes. In particular, I think Good Doctor sales and OTC-related input will appear in the numbers to some extent.

Ueda: Okay. Thank you. Lastly, my third question is about Cefiderocol.

Could you please explain the possibility of this subscription-type reimbursement model like you introduced today spreading globally beyond the UK or Sweden? If it were to spread globally, what level of revenue do you assume from each dose of this drug?

In addition, please tell me how long the contract period generally lasts for this type of contract and how sustainably you expect revenue to be generated.

Sawada: The subscription model is, in fact, being discussed in the US Congress. In that sense, I believe the subscription model is the revenue model that is closest to spreading wider.

However, even in such subscription model, there are differences depending on country. For instance, in Sweden, the payment for a fixed amount is guaranteed, and if there is an excess beyond that amount, it will be reimbursed through normal insurance. In contrast to this model where companies are able to capture the profits, in the UK, there appears to be a cap on payments. I think that the actual sales will differ depending on what kind of form the subscription model takes.

Relatively speaking, the UK and Sweden are countries with few resistant bacterial infections. Therefore, at present, I believe each country is setting this amount while scrutinizing factors such as market share. I think there will be a huge difference in sales amount depending on what kind of model is adopted by a country with a significant market share, such as the US.

Currently, when looking at the total market, it would be quite difficult unless sales amount to JPY100 billion to JPY200 billion of total subscription market globally. However, countries like Sweden and the UK are each generally calculating their market share at slightly low levels and setting the amount based on that. If all goes well in the end, we should be able to get close to that level.

However, this is premised on all countries adopting this method globally. Starting with the countries with the largest market share, I think the size will be one-half to one-third.

Naturally, each country understands very well that this would be pointless if it ended in one or two years. At this point, I believe there is a high likelihood that these countries will use several years or around five years as a benchmark with the option of further extending the period.

Ueda: I understood very well. Thank you. That's all.

Operator: The next question will be from Mr. Hashiguchi of Daiwa Securities. Please go ahead.

Hashiguchi: This is Hashiguchi of Daiwa Securities. Thanks. I have two questions.

First, regarding the subscription model for Cefiderocol, could you explain the new health reimbursement evaluation method in Germany?

Is this a method that is unique to Germany, or do you think it will be a third type of model subsequent to Sweden or the UK that will spread to other countries?

Sawada: In Germany, it is an insurance reimbursement, so it will be handled within the normal administration of pharmaceutical products. In that sense, I think the incentive is a little different. Rather, I think the discussion will be focused on what is the proper pricing and what is the proper reimbursement.

Hashiguchi: Okay. My second question is about the full-year forecast. Three months ago, I believe you explained that you have factored in costs related to business development such as M&A, including PMI and consulting fees.

Are these efforts ongoing? Also, this time, you lowered the forecast for SG&A expenses. Are changes in the situation around business development reflected in the updated forecast?

Hanasaki: Thank you for the question. Regarding deals, we are currently carrying out activities actively centered on business development to satisfy our future pipeline in Japan and overseas.

However, due to the elevated stock prices globally, the market value of companies is very high. We are looking for deals according to our value standard within our investing framework. In that sense, we aim to make business decisions keeping conscious not to grab deals at elevated price levels.

These fees are expenses that we consider to be essential to the STS2030 strategy. As such, we have included these fees to some extent in the second-half budget. We have reviewed the expenses from activities we had been conducting previously and lowered those costs, while shifting resources to the expenses necessary for the new STS2030 strategy. We revised the second half forecast this time within the context of this framework.

Hashiguchi: Thank you. That's all.

Operator: The next question will be from Mr. Sakai of Credit Suisse. Please go ahead.

Sakai: This is Sakai of Credit Suisse. I have three questions.

First, regarding the downward revision to the domestic business, you also revised down the forecast in October. I think, this time, it couldn't be helped that the infectious disease drugs like Xofluza were revised down. However, you have also revised down your forecast for Others like Cymbalta and Intuniv.

Is this because of the lack of sales capabilities? People who know SHIONOGI for a long time would consider this gradual downward revision to be unthinkable. How do you intend to fix this problem? I've asked about this to president Teshirogi many times, but what is not functioning?

I'm sure there is an impact from COVID-19, but this problem needs to be addressed, especially this year. There will be a generic of Cymbalta that's going to be launched. While this will require your attention, growth in Intuniv is also sluggish. I feel these are considerable risks. What are your views on this?

Sawada: I will answer your question. As you say, we share your strong sense of crisis.

In particular, we are aware that we need to grow sales of Intuniv. We are working on this situation, but we still didn't have a clear grasp of this matter at the time of the end of the first half. I think we didn't correctly forecast the shrinkage of the switching market for switching prescriptions.

However, there are other companies who have grown sales even under this situation, so we will pursue sales growth without using that as an excuse. Especially for Intuniv, there aren't that many target facilities. We intend to keep track of every single facility and cover the current status at the headquarters.

Sakai: What is the ratio of adults to children among Intuniv users. Is it around 5:5?

Sawada: Yes. However, we understand that we were in a phase where we should have particularly grown sales for adults. I think the biggest problem was that we couldn't increase sales for adults. We intend to carefully look at this in detail from this perspective.

Sakai: Okay, thank you. Next, I would like to ask two or three questions at once regarding the pipeline.

Regarding S-872600, I believe this is a nasal absorption vaccine that is still in the preclinical stage. I had been focusing on this vaccine with some expectation given that it is a nasal type. However, it seems like it has been lingering in the preclinical stage for quite a bit of time.

Please tell me if there are any updates, especially please tell us what level the potential for expanding adaptation to COVID-19 is now.

Also, in terms of Cabotegravir, I don't know if my understanding is wrong, but this is two shots at a time, correct? That's just something I want to confirm. Could you answer those two questions, please?

Sawada: First, I will answer the second question. We have to shot Cabotegravir and Rilpivirine, respectively. So, two shots need to be administered.

Sakai: Is it possible to make one shot?

Sawada: At present, the storage conditions are different, so I think that would be difficult. It would also result in an increased amount of liquid.

Sakai: Okay.

Sawada: Regarding your question about the nasal vaccine, we need to place the foremost priority on advancing the COVID-19 vaccine right now. As I explained earlier, we have no choice but to steadily make progress in preparing for Phase 3 clinical trials of COVID-19 vaccine. As a result, the resources used for that purpose will also be considerable.

At the moment, the foremost manufacturing priority is on the current COVID-19 vaccine, so there have been some negative consequences of that.

Sakai: It doesn't mean at all that the priority has gone down, right?

Sawada: Yes. It means that the priority of COVID-19 is extremely high.

Sakai: Okay. Thank you very much.

Operator: The next question will be from Mr. Kohtani of Nomura Securities. Please go ahead.

Kohtani: This is Kohtani of Nomura Securities. I have three questions.

My first question is about S-648414. In your answer to a previous question, you said that this is slightly delayed. You mentioned that it is a little difficult to formulate an injection. Regarding this point, you were already considering the diversion to injection back when you held briefing meetings in 2018 or 2019. So, why is this delayed right now?

In any case, I think you would need to demonstrate the effects of the oral preparation, so it would be better to proceed with both trials. Is it correct to understand that these trials have been stopped, too?

Sawada: Certainly, the R&D resources are concentrated in COVID-19 projects. There is slightly an issue with suppressing skin irritation and local irritation in terms of injections.

If there isn't an improvement to these issues, or if it is difficult to solve, then it would be meaningless to push this development forward. Therefore, I believe we will need to strike a balance with that outlook.

Kohtani: About how long does this process usually take? Is it three months, or will it take around one year? How should I understand this?

Sawada: If it goes well, it could be done quickly. But if it does not go well, it will not make much progress. In that sense, it is difficult to make any promises.

Kohtani: If that is the case, could you reflect that into the pipeline slides at the end of the presentation? Furthermore, if you could do so at the time you find out, it would be very helpful. Could you consider doing so, please?

Sawada: We are currently making considerations about disclosing this information after sorting it out at the development department, including the case where it will be paused for some time and all the internal procedures. I believe the plan will be fine-tuned most likely by the end of the fiscal year or later.

Kohtani: Okay. My second question is about the COVID-19 vaccine. There are various academic papers being published that verify the effectiveness of vaccines and antibodies against various mutant virus. As far as I can see, the common factor is the E484K mutation found in the protein in both the South African and Brazilian-type strains, and this mutants show the highest resistance. It seems that the affinity of the receptor binding domain is weakened.

Given that so many mutants have already appeared and regions that have not been able to contain the spread at all, I think there is a high possibility that further mutants will appear in the future. If that is so, then unless the vaccine is able to display some degree of effectiveness against these mutants as a starting point, then I think the commercial potential of the vaccine will be considerably reduced.

However, if too much time is spent, then as you say, there is a possibility that the Phase 3 trials will not be a placebo-controlled study. Could you please tell me your thoughts about mutations and what kind of initiatives you plan to take going forward? That is my second question.

Sawada: I believe this is a topic in which a considerable degree of discussion is being held not only by our Company but also by many parties, including regulatory agencies about what to do next.

In the case of influenza, vaccines are premised on these mutations occurring every year. We respond to them every year, and the regulatory authorities are supposed to accept them. But in the case of COVID-19, there hasn't been an agreement reached as to what extent would be tolerable and what kind of data would be needed to support that. Therefore, I think this is a topic that will be discussed going forward.

To some extent, they may accept vaccines that have shown a proper medicinal effect based on a placebo-controlled study after some minor changes. But they may need a certain degree of data for that. This is a topic that will probably be discussed going forward. Naturally, I think that each company is thinking about how to deal with mutant agents.

Kohtani: What I wanted to ask was whether you have designed the vaccine from the outset so that it is effective against these mutants. Have you considered this?

Sawada: At the outset of vaccine development, the Brazilian and UK-type strains hadn't been found yet. Obviously, we have designed the vaccine in response to a virus closer to the native strain.

Kohtani: Okay. Lastly, I would like to know how I should think about the status of competitors against Cabotegravir, as far as you can answer.

The reason why I ask about this is that there are various other drugs under development like Lenacapavir. As far as I see, Lenacapavir, it requires subcutaneous administration once every three or six months. This is still for multidrug-resistant HIV, so it's not being used for new diagnosis yet. Also, Gilead don't show any data about a long-term drug regimen, so I don't think it will be that easy for it to be a threat to Cabotegravir.

Furthermore, it currently combines an oral drug and injection drug. In that sense, I think it is a little inferior to Cabotegravir, with is only an injection drug, in terms of convenience. Therefore, unless a partner drug comes out, should Lenacapavir be seen as a considerable threat at this point?

Also, in terms of Islatravir, by Merck, I believe this is a drug that is administered orally once a week. There are also obvious considerations for this drug too, such as the results of long-term studies.

However, as far as I can see, a weekly oral administration wouldn't change the convenience much compared to a monthly oral administration, so I believe preventing this monthly oral administration would pose a threat.

I think it's difficult to comment on this, but could you tell me if there's anything wrong with what I just said? Also, can you tell me if there's any information you can add to that? That's my last question.

Sawada: There are concerns regarding the danger of being more prone to forgetting a monthly oral administration than an injection. As you stated, it is unclear whether these drugs could be a real threat to Cabotegravir until we see the proper data for long-term dosage.

Even with regards to the two-drug regimen, I don't think that the medical professionals will accept the drug unless there is a considerable accumulation of data on long-term dosage. In consideration of that, I think it will be difficult to increase trust in the drug unless there is more reliable data regarding each of those drugs. I think it will be difficult for the next four to five years.

Kohtani: Thinking straightforwardly, I believe the greatest threat would be when Lenacapavir partners with Islatravir. Would you say this is accurate?

Sawada: Even in that case, they would still need to properly gather data for the next four to five years. They need to think about the target subjects and whether the drug can be taken orally instead of an injection.

Kohtani: Okay. Thank you.

Kyokawa: Thank you for the many questions. We are very sorry for not being able to answer some of the questions. Please call our Corporate Communications Department to ask any other questions.

We would now like to end the third-quarter conference call for the fiscal year ending March 2021 of SHIONOGI. Thank you, everyone, for joining us today despite your busy schedules.

[END]