1st Half of Fiscal 2023 Financial Results

October 31, 2023

Shionogi & Co., Ltd.

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Agenda

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- **FY2023 Financial Forecasts (P.13-18)**
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- **Updates on COVID-19 Treatment (P.21-24)**
- **Main Activities and Achievements in Pipeline (P.25-33)**
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Overview of 1st Half FY2023 Financial Results

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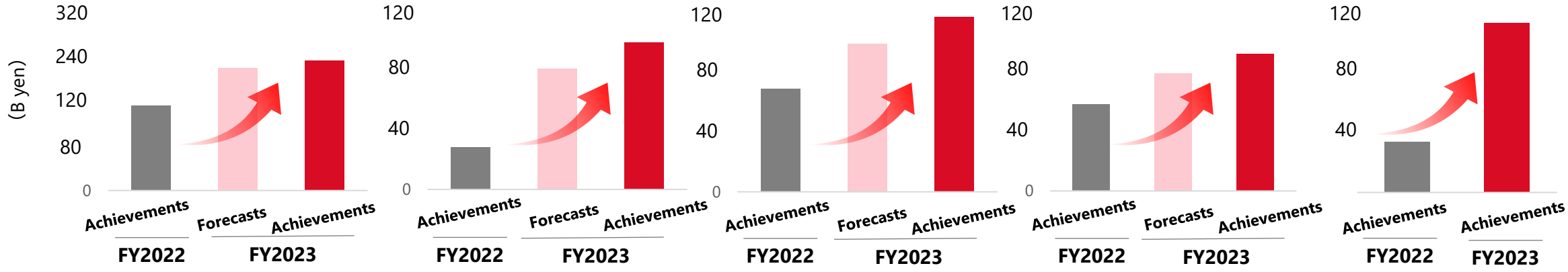
Financial Highlights

- **Revenue and all profit items increased year-on-year, with sales and profits significantly exceeding expectations**
- **Continuing from 1Q, sales revenue and various profits reached record highs in the first half as well**

	Revenue	Operating profit	Profit before tax	Profit attributable to owners of parent	EBITDA*
1st Half	**230.5** B yen	**98.1** B yen	**115.6** B yen	**90.6** B yen	**114.2** B yen
Y on Y	**+52.9** %	**+247.6** %	**+70.1** %	**+58.2** %	**+234.6** %
Forecast Comparison	**+ 6.2** %	**+ 21.9** %	**+18.0** %	**+16.1** %	



* 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

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results	Change(%)	Change
	Full year	1H					
Revenue	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**
Operating profit	150.0	80.5	**98.1**	**121.9**	28.2	**247.6**	**69.9**
Profit before tax	192.5	98.0	**115.6**	**118.0**	68.0	**70.1**	**47.6**
Profit attributable to owners of parent	155.0	78.0	**90.6**	**116.1**	57.3	**58.2**	**33.3**

Exchange Rate（Average）

	FY2023 Forecasts	FY2023 1H Results
USD($) – JPY(¥)	**130**	**141.06**
GBP(£) – JPY(¥)	**160**	**177.63**
EUR(€) – JPY(¥)	**140**	**153.46**

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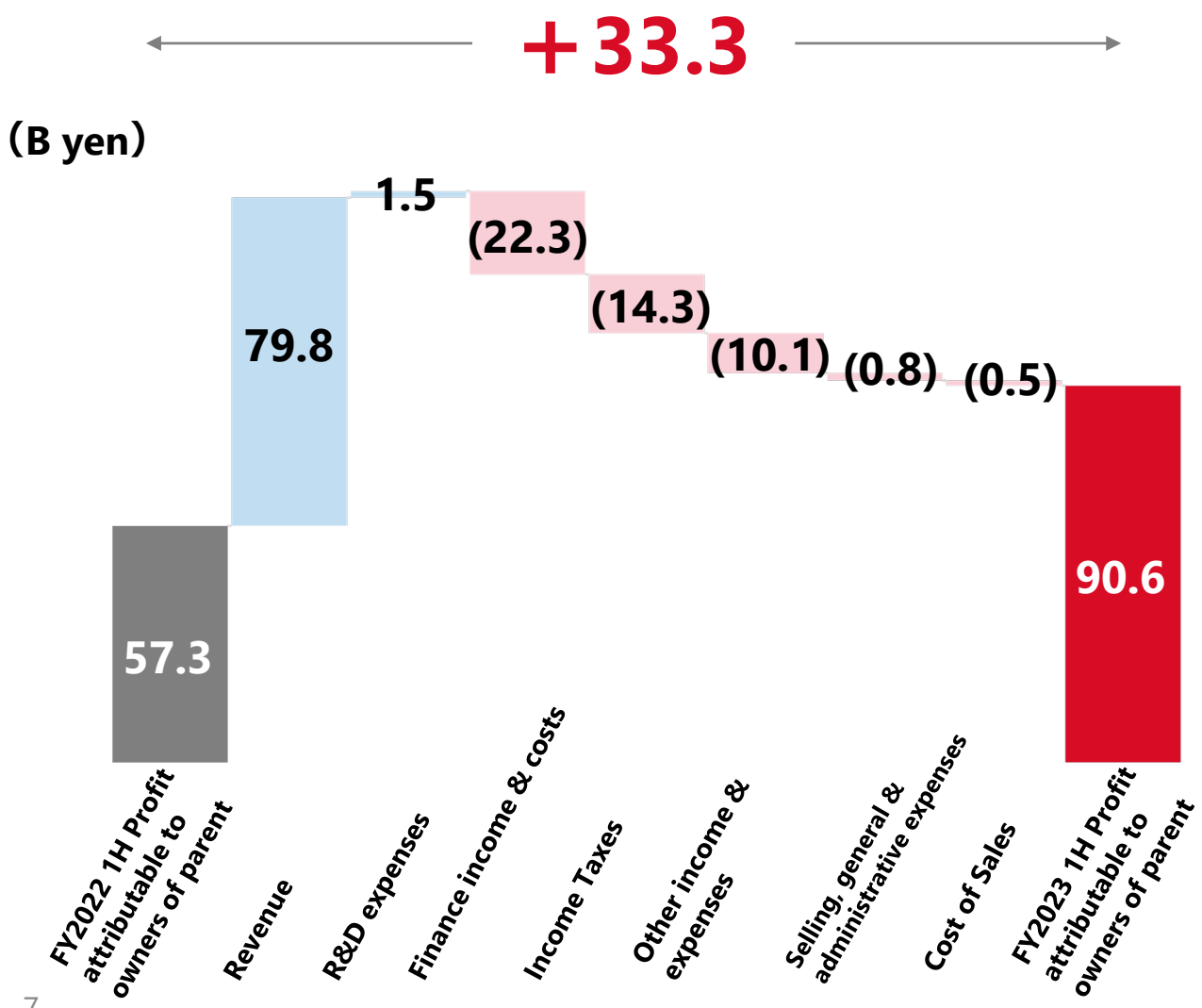
Statement of Profit or Loss

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Revenue	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**
Cost of Sales	15.3 69.0	14.5 31.5	**12.1** **27.9**	**88.5**	18.2 27.4	**1.9**	**0.5**
Gross profit	381.0	185.5	**202.7**	**109.2**	123.4	**64.2**	**79.2**
Selling, general & administrative expenses, R&D expenses total	50.9 229.0	47.7 103.5	**41.8** **96.5**	**93.2**	64.5 97.2	**(0.8)**	**(0.7)**
Selling, general & administrative expenses	28.9 130.0	24.9 54.0	**21.4** **49.2**	**91.2**	32.1 48.5	**1.6**	**0.8**
R&D expenses	22.0 99.0	22.8 49.5	**20.5** **47.2**	**95.4**	32.3 48.7	**(3.1)**	**(1.5)**
Other income & expenses	(2.0)	(1.5)	**(8.1)**	**-**	2.0	**-**	**(10.1)**
Operating profit	33.3 150.0	37.1 80.5	**42.6** **98.1**	**121.9**	18.7 28.2	**247.6**	**69.9**
Finance income & costs	42.5	17.5	**17.5**	**100.0**	39.8	**(56.0)**	**(22.3)**
Profit before tax	42.8 192.5	45.2 98.0	**50.1** **115.6**	**118.0**	45.1 68.0	**70.1**	**47.6**
Profit attributable to owners of parent	155.0	78.0	**90.6**	**116.1**	57.3	**58.2**	**33.3**

Main Variation Factors of Profit attributable to owners of parent (Y on Y)



Revenue

- Increase：Domestic sales, Overseas subsidiaries /export, Royalty income

Other income & expenses

- Increase：Costs related to implementation of early retirement program (Special Notes for 2Q)
- decrease：Sale of investment real estate in FY22 (2.4 B yen)

Finance income & costs

- Decrease in income: Received dividend from ViiV
  - FY2022 dividend increased temporarily

⇒ Dividends are progressing as planned, excluding temporary factors

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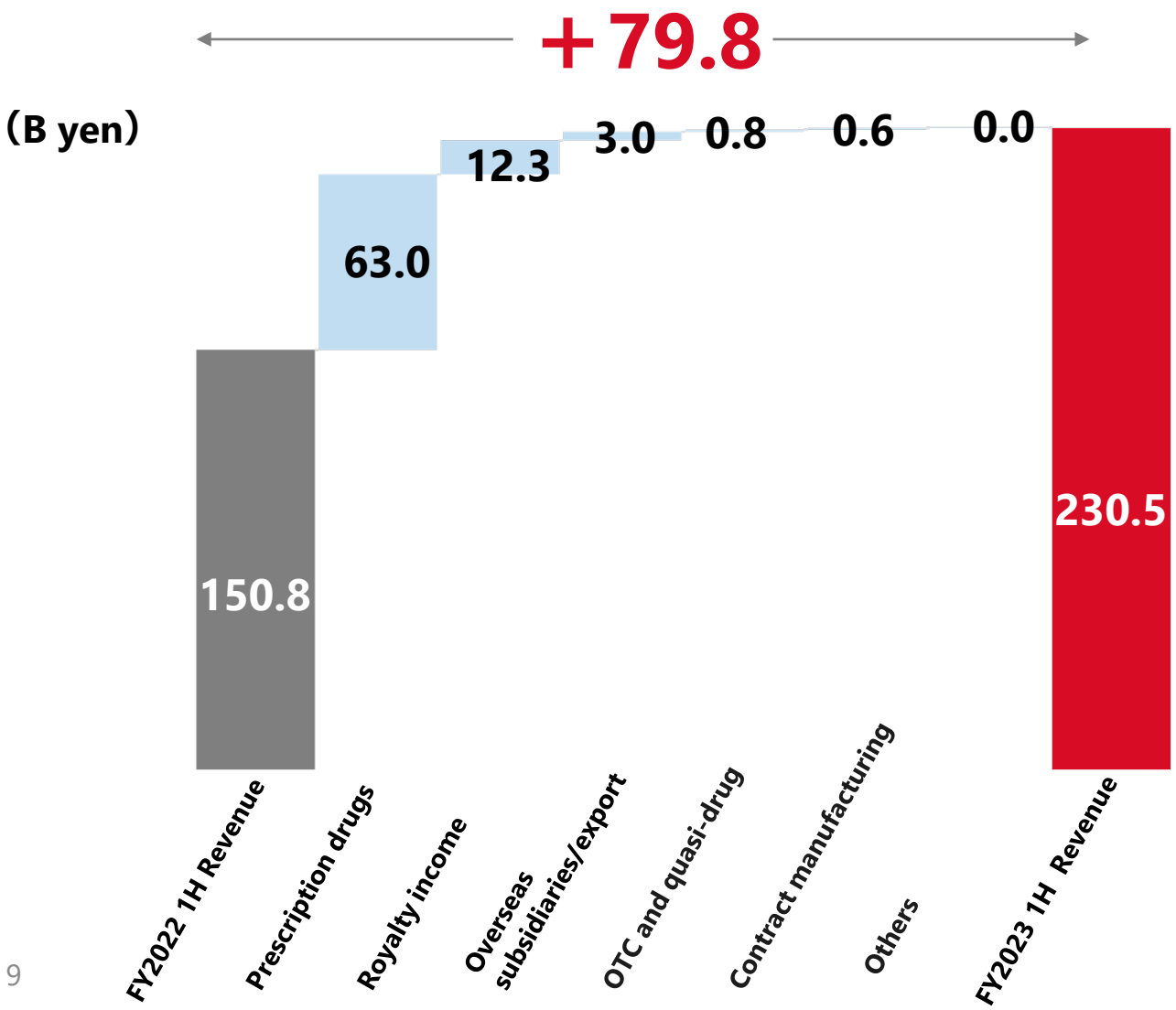
Revenue by Segment

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Prescription drugs	134.1	87.4	**96.4**	**110.2**	33.4	**188.8**	**63.0**
Overseas subsidiaries/export	96.6	28.0	**22.9**	**81.9**	19.9	**15.1**	**3.0**
Shionogi Inc.（US）	13.6	6.7	**8.1**	**121.8**	7.4	**10.3**	**0.8**
Fetroja	-	-	**6.5**	**-**	4.7	**37.6**	**1.8**
Shionogi B.V.（EU）	11.5	5.4	**6.1**	**112.5**	4.3	**43.0**	**1.8**
Fetcroja	-	-	**4.6**	**-**	3.2	**41.2**	**1.3**
Ping An Shionogi/C&O	58.0	13.2	**5.2**	**39.7**	5.6	**(6.4)**	**(0.4)**
Others	13.4	2.7	**3.4**	**127.6**	2.7	**28.3**	**0.8**
Contract manufacturing	13.8	7.3	**7.9**	**108.3**	7.4	**7.8**	**0.6**
OTC and quasi-drug	15.0	6.8	**7.1**	**104.1**	6.3	**13.1**	**0.8**
Royalty income	189.5	86.9	**95.6**	**110.0**	83.3	**14.8**	**12.3**
HIV franchise	185.0	86.0	**94.5**	**109.8**	80.4	**17.6**	**14.1**
Others	4.5	0.9	**1.1**	**125.7**	2.9	**(61.5)**	**(1.8)**
Others	1.0	0.5	**0.6**	**127.8**	0.6	**5.6**	**0.0**
Total	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**

Main Variation Factors of Revenue (Y on Y)



Prescription drugs

- Increase : Sales of Xocova and Xofluza
  : Receipt of Lump-sum income for transfer of ADHD drug
  : Returns of Xofluza and Rapiacta in FY2022 (5.3 B yen)
- Decrease: Sales of ADHD drug

Royalty income

- Increase: Strong sales of ViiV's HIV franchise

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (Fetroja、Fetcroja)
- Decrease: Change in Osphena sales scheme

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Prescription Drugs in Japan

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Infectious disease drugs	65.7	40.0	**49.0**	**122.5**	(0.6)	**-**	**49.6**
COVID-19 related products + Influenza franchise	57.3	35.8	**44.4**	**124.1**	(5.0)*	**-**	**49.4**
Cymbalta	4.2	2.1	**2.1**	**98.1**	3.0	**(31.2)**	**(1.0)**
OxyContin franchise	4.1	2.1	**2.2**	**103.2**	2.3	**(5.3)**	**(0.1)**
Symproic	4.9	2.3	**2.1**	**92.4**	1.6	**28.8**	**0.5**
Actair	1.0	0.4	**0.3**	**78.0**	0.3	**20.2**	**0.1**
Mulpleta	0.1	0.1	**0.0**	**78.4**	0.1	**(7.1)**	**(0.0)**
Pirespa	1.9	1.1	**1.0**	**95.6**	1.4	**(25.5)**	**(0.3)**
Others	52.1	39.3	**39.6**	**100.6**	25.3	**56.5**	**14.3**
ADHD drug (Intuniv and Vyvanse)**	25.0	25.0	**25.0**	**-**	10.1	**147.8**	**14.9**
Prescription drugs	134.1	87.4	**96.4**	**110.2**	33.4	**188.8**	**63.0**

COVID-19 related products
- Xocova
- COVID-19 vaccines

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE

* Returns of Xofluza and Rapiacta

** Includes Lump-sum income from transfer of ADHD drug

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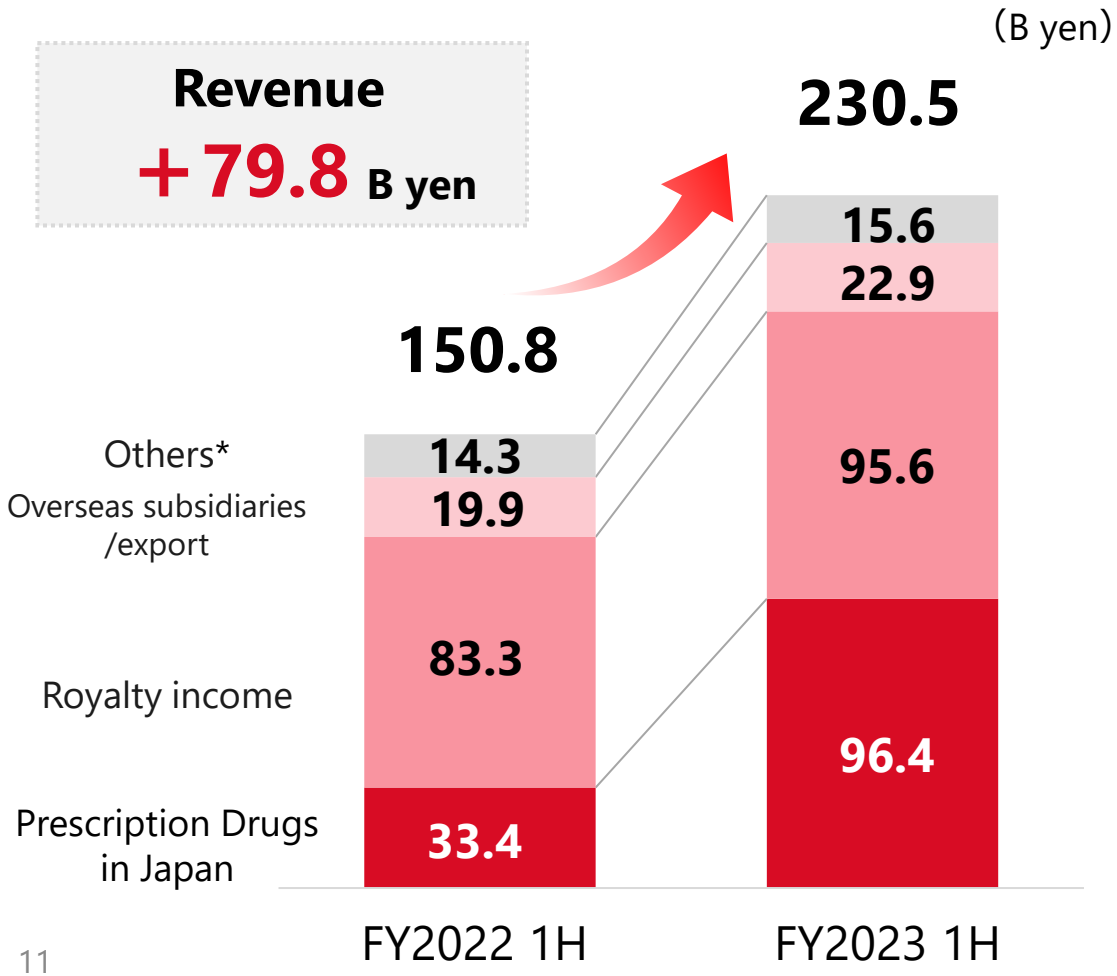
Top-line grew significantly due to expansion of in-house sales

Continuing from 1Q, sales continued to increase in all businesses



Key drivers of top-line growth

- Domestic : Xocova sales strongly drive top-line growth
  : Strong growth of Influenza franchise
- Overseas subsidiaries : Strong growth of Cefiderocol（Fetroja, Fetcroja）
- Royalty income : Growth of Dovato and expansion of share of cabotegravir
- Others : Growth of Contract manufacturing and OTC and quasi-drug

* Total of Contract manufacturing and OTC and quasi-drug, others

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1st Half Results and Future Outlook

Steady progress in transforming the company into a company that can expand globally

Top-line growth

Achieved record highs in sales revenue and all profit items

- Significant growth in all businesses (Y on Y)
- Revenue and various profit items exceeded budget

Establishment of growth drivers

Progress in development pipeline

- Safety and tolerability data from Phase 1 study of S-309309 presented at Obesity week
- Started development of a combination of cefiderocol + Xeruborbactam

Overview of 1st Half FY2023 Financial Results

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Regarding changes in the breakdown of earnings forecasts

As top line growth is steady, initial forecasts for revenue and various profit items remain unchanged

Revenue

Upward Revision

- Sales increase of COVID-19 related products Influenza franchise
  - Xocova market penetration exceeds expectations in Japan and predicts resurgence of respiratory infections this winter
- Increase of Royalty income
  - Strong sales of ViiV's HIV franchise
- Sales increase of Shionogi Inc., Shionogi B.V.
  - Strong growth of Cefiderocol（Fetroja, Fetcroja）

Downward revision

- Decrease of Overseas subsidiaries/export (Ping An Shionogi/C&O and Others)
  - Temporarily excluded from sales due to uncertainty regarding Xocova approval in Asia
    - > Continued discussions with national authorities

Selling, general & administrative expenses, R&D expenses

- Decrease in selling, general & administrative expenses
  - Sales costs not recorded after approval of Xocova in Asia
- Increase of R&D expenses
  - Accelerate investment for overseas growth of vaccines and Xocova

Financial Results

(Unit：B yen)

	FY2023 Forecast		FY2022 Results	Y on Y	
	Full year	2H	Full year	Change (%)	Change
Revenue	450.0	219.5	426.7	**5.5**	**23.3**
Operating profit	150.0	51.9	149.0	**0.7**	**1.0**
Profit before tax	192.5	76.9	220.3	**(12.6)**	**(27.8)**
Profit attributable to owners of parent	155.0	64.4	185.0	**(16.2)**	**(30.0)**

Exchange Rate (Average)

	FY2023 Forecasts (May. 10)	FY2023 1H Results	FY2023 Forecasts (Oct. 31)
USD($) – JPY(¥)	**130**	**141.06**	**141**
GBP(£) – JPY(¥)	**160**	**177.63**	**173**
EUR(€) – JPY(¥)	**140**	**153.46**	**151**

Statement of Profit and Loss

(Unit：B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Revenue	450.0	**450.0**	**-**	233.0	**219.5**	**(13.5)**	426.7	5.5	23.3
Cost of Sales	15.3 69.0	13.2 **59.5**	**(9.5)**	16.1 37.5	14.4 **31.6**	**(5.9)**	14.6 62.2	(4.4)	(2.7)
Gross profit	381.0	**390.5**	**9.5**	195.5	**187.8**	**(7.7)**	364.4	7.2	26.1
Selling, general & administrative expenses, R&D expenses total	50.9 229.0	51.3 **231.0**	**2.0**	53.9 125.5	61.3 **134.5**	**9.0**	47.8 203.9	13.3	27.1
Selling, general & administrative expenses	28.9 130.0	26.4 **119.0**	**(11.0)**	32.6 76.0	31.8 **69.8**	**(6.2)**	23.8 101.5	17.2	17.5
R&D expenses	22.0 99.0	24.9 **112.0**	**13.0**	21.2 49.5	29.5 **64.8**	**15.3**	24.0 102.4	9.4	9.6
Other income & expenses	(2.0)	**(9.5)**	**(7.5)**	(0.5)	**(1.4)**	**(0.9)**	(11.5)	-	2.0
Operating profit	33.3 150.0	33.3 **150.0**	**-**	29.8 69.5	23.6 **51.9**	**(17.6)**	34.9 149.0	0.7	1.0
Finance income & costs	42.5	**42.5**	**-**	25.0	**25.0**	**-**	71.3	(40.4)	(28.8)
Profit before tax	42.8 192.5	42.8 **192.5**	**-**	40.6 94.5	35.0 **76.9**	**(17.6)**	51.6 220.3	(12.6)	(27.8)
Profit attributable to owners of parent	155.0	**155.0**	**-**	77.0	**64.4**	**(12.6)**	185.0	(16.2)	(30.0)

Revenue by Segment

(Unit：B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Prescription drugs	134.1	**167.0**	**32.9**	46.7	**70.6**	**24.0**	179.7	(7.1)	(12.7)
Overseas subsidiaries/export	96.6	**49.2**	**(47.4)**	68.6	**26.2**	**(42.4)**	42.5	15.7	6.7
Shionogi Inc.（US）	13.6	**17.0**	**3.3**	7.0	**8.8**	**1.9**	15.4	9.7	1.5
Fetroja	-	**-**	**-**	-	**-**	**-**	10.0	-	-
Shionogi B.V.（EU）	11.5	**13.0**	**1.5**	6.1	**6.9**	**0.8**	9.1	43.7	4.0
Fetcroja	-	**-**	**-**	-	**-**	**-**	6.6	-	-
Ping An Shionogi/C&O	58.0	**12.1**	**(46.0)**	44.8	**6.8**	**(38.0)**	12.0	0.7	0.1
Others	13.4	**7.1**	**(6.3)**	10.7	**3.7**	**(7.0)**	6.0	18.4	1.1
Contract manufacturing	13.8	**16.4**	**2.6**	6.5	**8.4**	**2.0**	15.3	6.7	1.0
OTC and quasi-drug	15.0	**14.8**	**(0.2)**	8.2	**7.7**	**(0.5)**	13.1	12.4	1.6
Royalty income	189.5	**201.2**	**11.7**	102.6	**105.7**	**3.1**	174.7	15.2	26.5
HIV franchise	185.0	**196.5**	**11.5**	99.0	**102.0**	**3.1**	168.5	16.7	28.1
Others	4.5	**4.7**	**0.2**	3.6	**3.6**	**-**	6.2	(24.1)	(1.5)
Others	1.0	**1.5**	**0.5**	0.5	**0.8**	**0.3**	1.3	14.2	0.2
Total	450.0	**450.0**	**-**	230.0	**219.5**	**(13.5)**	426.7	5.5	23.3

Prescription Drugs in Japan

(Unit：B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Infectious disease drugs	65.7	**97.5**	**31.8**	25.7	**48.5**	**22.8**	112.1	(13.0)	(14.6)
COVID-19 related products + Influenza franchise	57.3	**88.6**	**31.3**	21.5	**44.2**	**22.7**	103.6	(14.5)	(15.0)
Cymbalta	4.2	**4.2**	**-**	2.0	**2.1**	**0.0**	5.4	(23.5)	(1.3)
OxyContin franchise	4.1	**4.3**	**0.1**	2.0	**2.1**	**0.1**	4.4	(3.5)	(0.2)
Symproic	4.9	**4.9**	**-**	2.7	**2.8**	**0.2**	3.4	44.6	1.5
Actair	1.0	**1.0**	**-**	0.6	**0.7**	**0.1**	0.5	91.0	0.5
Mulpleta	0.1	**0.1**	**-**	0.1	**0.1**	**0.0**	0.1	25.9	0.0
Pirespa	1.9	**1.9**	**-**	0.9	**0.9**	**0.0**	2.5	(24.4)	(0.6)
Others	52.1	**53.1**	**1.0**	12.8	**13.5**	**0.8**	30.6	73.6	22.5
ADHD drug (Intuniv and Vyvanse)**	25.0	**25.0**	**-**	-	**-**	**-**	20.6	21.4	4.4
Prescription drugs	134.1	**167.0**	**32.9**	46.7	**70.6**	**24.0**	179.7	(7.1)	(12.7)

COVID-19 related products
- Xocova
- COVID-19 vaccines

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE

* Returns of Xofluza and Rapiacta

** Includes Lump-sum income from transfer of ADHD drug

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Shareholder Return

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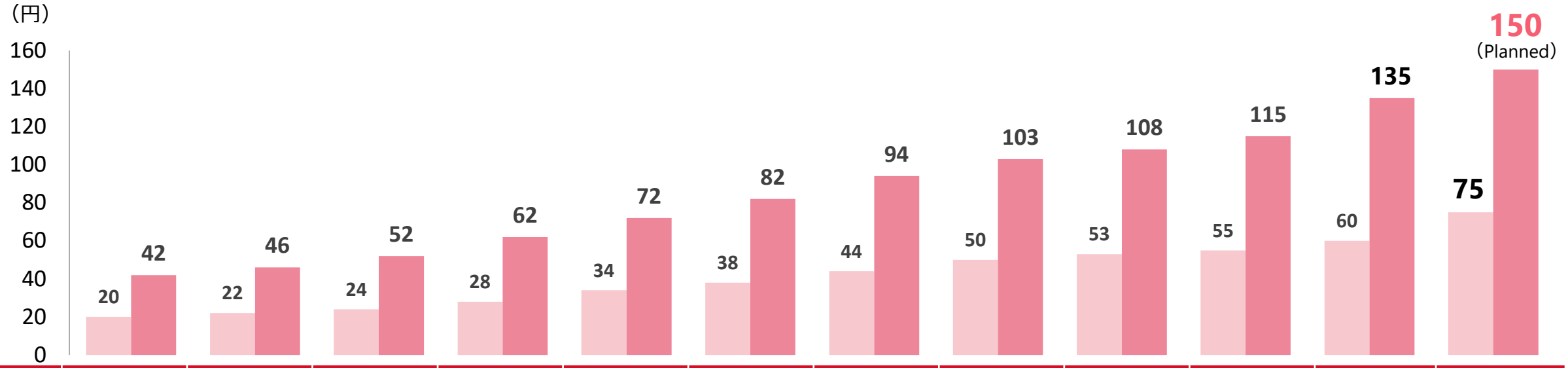
Flexible and Prompt Capital Strategy

- **Shareholder return policy through which shareholders can feel our growth**
  - Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
  - Increased dividend by 15 yen from the previous interim period
  - Plan to increase dividend again for the 12th consecutive year in FY2023



FY		12	13	14	15	16	17	18	19	20	21	22	23
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	75 B yen**
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	-
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9	4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.5 (expected)

Values calculated based on IFRS after 2019

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020 ** Total amount of acquisition cost: 75 billion yen (maximum)

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Updates on COVID-19 Treatment

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Xocova: Development Plan

Promoting development that meets medical and social needs

SCORPIO-HR trial*	**Purpose: Verify the effectiveness of improving clinical symptoms in outpatient COVID-19 cases, including patients at risk of developing severe illness** • Target number of the enrollment : 2,000 cases • The completion of enrollment will be expected by the end of this year • Discussions with FDA regarding efficacy verification against Long COVID
SCORPIO-PEP trial	**Purpose: Verify the effectiveness of suppressing the onset of COVID-19 symptoms in close contacts** • Target number of the enrollment: 2,200 cases • The enrollment progressing smoothly
Pediatric trial	**Purpose: Expand indication to children with limited treatment options** • Under 6-12 years old: Clinical trials underway in Japan • In parallel, we are preparing a global pediatric trial
STRIVE trial*	**Purpose: Verification of the efficacy and safety of ensitrevir in hospitalized critically ill patients** • Target number of the enrollment: 1,500 cases

*Global Phase 3 supported by NIH (National Institutes of Health)

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Xocova: New Data Announced

Effectiveness against Long COVID*

Results after 1 year of treatment with ensitrelvir

- Suggests the possibility of reducing the risk of occurrence over a long period of time
  - A decreasing trend in the risk of developing Long COVID was confirmed. 25% reduction compared to placebo.
- Reduce the percentage of patients who develop commonly reported neurological symptoms
  - In particular, for symptoms of decreased concentration/thinking ability and forgetfulness, the risk was significantly reduced by 68% and 72%, respectively

Suggests the need for early treatment with antiviral drugs

Post-Marketing Survey**

- Accumulation of safety and efficacy information from actual use
  - Safety: No new safety concerns identified
  - Effectiveness:
    - > Median time to resolution of all symptoms of COVID-19 (median) : 156.0 hours
    - > Recovery time to normal temperature (median): 36.0 hours
    - > Hospitalization: 4 cases/1584 cases, Death: 0 cases/1584 cases

Results similar to clinical trials were obtained

* Announced at ESWI 2023. Data from administration of 125mg, the emergency approved dose in Japan

** Presented at IDWeek 2023. Post-marketing surveillance on safety and efficacy targeting 3,000 patients: 1,682 patients registered as of July 20, 2023. Number of cases evaluated for safety: 1,589 cases, Number of cases evaluated for efficacy: 1,584 cases

Xocova: New Data Announced

Taste and Smell disorders

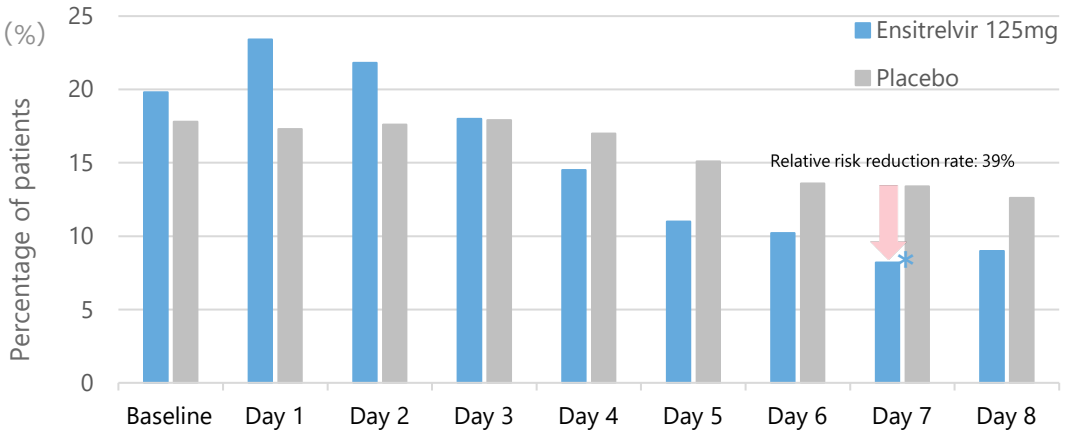
It is a characteristic symptom of COVID-19, and the period of illness tends to be longer than other symptoms

Nature Medicine, 2022; 28, 1031-1041

Effectiveness on taste and smell disorders* -Phase 2/3 phase clinical trial Additional analysis of Phase 3 part-

Percentage of patients with symptoms of taste or smell disorders

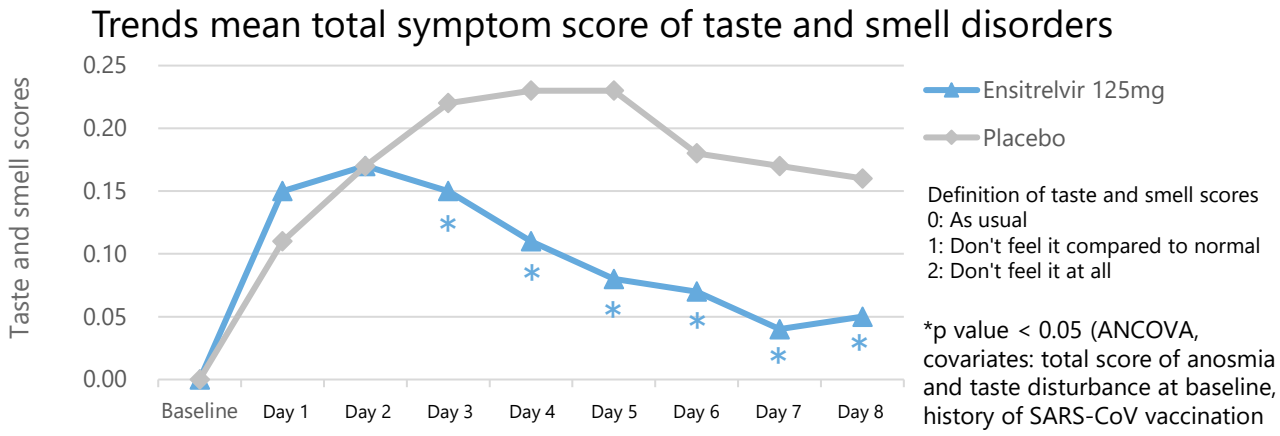
Significantly reduced the proportion of patients with taste or smell disorders on day 7 compared to the placebo group (relative risk reduction rate: 39%)



＊p value＜0.05 (Mantel-Haenszel test stratified by SARS-CoV-2 vaccination history

Trends in symptom scores in a group of patients without taste or smell disorders before beginig of the treatment

After the 3rd dose, the total score of taste or smell disorders was significantly suppressed compared to placebo



Definition of taste and smell scores
0: As usual
1: Don't feel it compared to normal
2: Don't feel it at all

*p value < 0.05 (ANCOVA, covariates: total score of anosmia and taste disturbance at baseline, history of SARS-CoV vaccination (Yes or No))

Early treatment within 3 days from the onset with ensitrelvir suggests early improvement and prevention effects on taste and smell disorders

* Presented at Dweek 2023

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Main Activities and Achievements in Pipeline

Progress of Major Development Products

as of October 30, 2023

Disease area	Pipeline	Indication	Current stage	FY2023	FY2024	Note
Infection diseases	**S-268019**	COVID-19 (Vaccine)	Submission			
	Olorofim	Invasive aspergillosis	Phase 3	→ Completion of Phase 3 case registration (4Q)		
	S-337395	RSV infections	Phase 1	→ Phase 1 topline results		
	S-892216	COVID-19	Phase 1	→ Phase 1 topline results		
	S-743229	AMR (Urinary tract infection)	Phase 1	→		Conducting Phase 1
	S-649228	AMR (Various infectious diseases)	Preclinical			Start Preclinical
	S-268023	COVID-19 (XBB 1.5, Vaccine)	Preclinical			Start Preclinical
QOL Diseases with High Social Impact	**Zuranolone**	Depression	Phase 3	→ Phase 3 topline results (3Q)	→ Submission (4Q)	
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	→	→ Submission (4Q)	
	SDT-001	ADHD	Phase 3	→ Submission		
	Zatolmilast	Fragile X Syndrome	Phase 2/3	→ Phase 2/3 topline results (FY242Q)	→ Submission (FY25 1Q)	Rare Pediatric Disease Designation
	Redasemtide	Acute ischemic stroke	Phase 2b	→	→	
		Dystrophic epidermolysis bullosa	Phase 2	→	→ Submission (3Q)	
	S-309309	Obesity	Phase 2	→ Obtain Phase 2 data (FY24 1Q)	→ Phase 3 start	Publication of Phase 1 data during Obesity week
	S-531011	Solid tumor	Phase 1b/2	→	→ Phase 2 start (2Q)	
	S-151128	Chronic pain	Phase 1	→ Phase 1 topline results		

topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

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Progress of Vaccine Development

Efforts toward building a sustainable business model are progressing

COVID-19 Vaccine

- Establish a recombinant protein vaccine platform and aim for full-scale supply of vaccines against mutant strains in the fall/winter season of 2024
- Actions towards establishing a platform
  - Obtaining approval for S-268019
    - > Continuing discussion: Additional evaluation based on onset prevention trial* data
  - Application for changes based on clinical trial data for XBB1.5 strain vaccine
    - > Developing a monovalent vaccine for the XBB1.5 strain
    - > Scheduled to start case registration in 3Q of 2023

※ Platform
For vaccines that have been established as a platform, if there is a commitment to obtain data on quality, efficacy, safety, and immunogenicity after marketing, it is possible to apply for a complete change to the current recommended strain with the latest quality and preclinical test results

Development of new technology

- Universal vaccine
  - Creation of antigen for development of universal sarbecovirus vaccine completed
  - Steady progress toward clinical entry in 2024
- Nasal vaccine
  - "Research and development of influenza/new coronavirus nasal vaccines" was selected as a vaccine/new modality research and development project solicited by AMED's*2 SCARDA*3

*1 Global Phase 3 NCT05212948
*2 Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
*3 Japan Agency for Medical Research and Development

Strengthen Pipeline by Making Qpex Biopharma a Wholly Owned Subsidiary

As a leading company in infectious diseases, further accelerating efforts to overcome AMR*1

Driving the development of a combination of the β-lactamase inhibitor xeruborbactam with β-lactam antibiotics

S-649228: xeruborbactam＋cefiderocol

- Injection in combination with cefiderocol
- Phase 1 trial scheduled to start in Q1 2024

Future studies to assess the utility of cefiderocol with xeruborbactam in the treatment of infections due to AMR

S-743229: xeruborbactam＋ceftibuten

- Oral formulation in combination with the cephem antibiotic ceftibuten
- Phase 1 trial ongoing

Combined effect of xeruborbactam against Enterobacteriaceae, which is a problem in AMR*2

	MIC_{90}*3	
	ESBL*4 (N=515)	CRE*5 (N=292)
Meropenem (IV)	0.06	>64
+Xeruborbactam	**≤0.03**	**0.06**
Cefepime (IV)	>64	>64
+Xeruborbactam	**≤0.03**	**0.25**
Ceftibuten (oral)	>64	>64
+Xeruborbactam	**≤0.03**	**0.06**

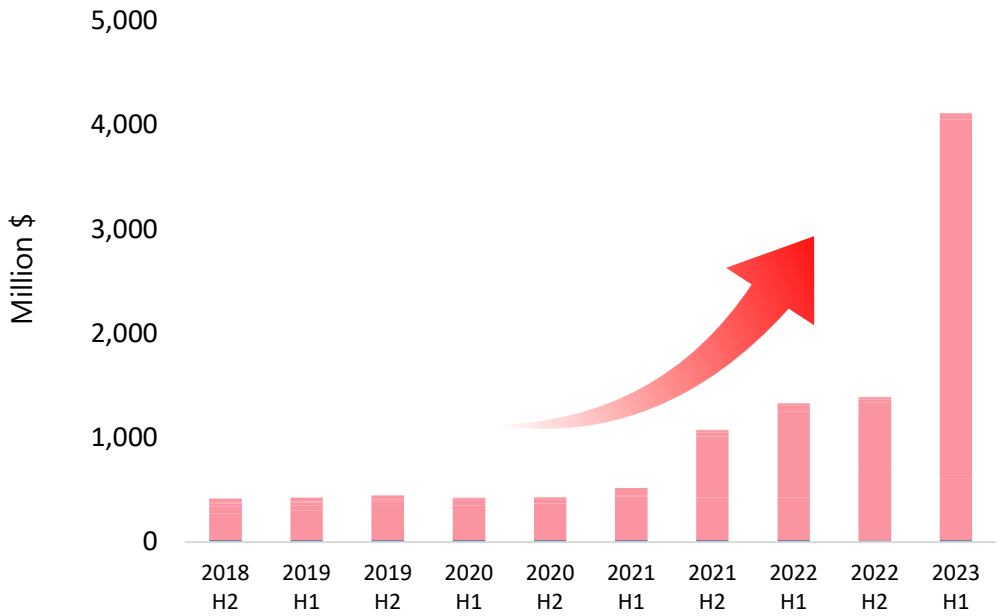
*1 Antimicrobial resistance *2 Olga Lomovskaya, IDWeek 2023, Oct 11-15, Boston, MA *3 Minimum Inhibitory Concentration (μg/mL) *4 Extended Spectrum β-Lactamase *5 Carbapenem-Resistant Enterobacterales

Funded in whole or in part with federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA) under OTA number HHSO100201600026C.

S-309309： Anti-Obesity Drug Market and Strengths of S-309309

An oral agent with a revolutionary mechanism provides an innovative option for the ever-expanding obesity market

Anti-obesity drug market in US



The obesity market is expanding explosively with the entry of GLP-1 injection into the market

Differentiating points of S-309309 (MGAT2* inhibitor)

- **Strong inhibition of triglyceride resynthesis in small intestinal epithelial cells**
  - Suppression of food intake through increased secretion of appetite regulators
  - Suppresses absorption of triglycerides
  - Increase of energy expenditure for enhance β-oxidation of accumulated fatty acids

  ⇒ Demonstrated greater weight reduction in preclinical studies
- **Offering non-injectable, small molecule option**
  - Reducing the financial burden on patients
  - Additive effect of combination with GLP-1 analogs (including orals)
- **Good PK and safety, tolerability**
  - Publication of Phase 1 data（Next page）

* Monoacylglycerol transferase 2 (App : P.34)

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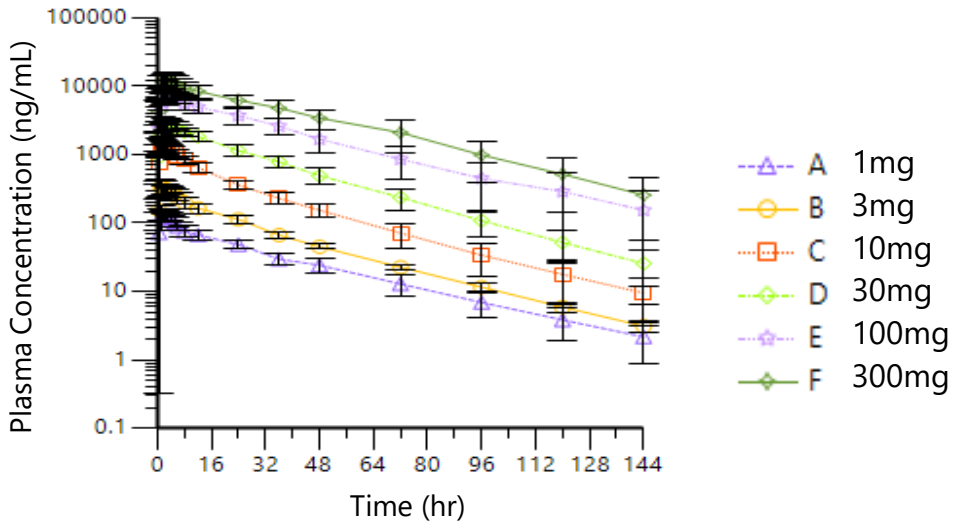
S-309309： Phase 1* Data Published during Obesity Week

There were no safety concerns, and the drug showed an excellent PK profile after single and multiple administrations

PK profile and Selection of target concentration



Phase 2 dose was determined based on the above results and target plasma concentration

Phase 2 trial progressing as planned after achieving FPI in July

Summary

Good PK profile

- Can be administered once a day (half-life: 20-24hr), linearity confirmed, small individual differences (variation in Cmax/AUC)
- No difference in PK between healthy and obese subjects
- No food effect on PK exposure, no drug-drug interaction with midazolam (CYP3A)

Well tolerability

- All AEs were mild, no dose-dependent increase in AE incidence rate
  - No serious side effects including gastrointestinal disorders
- No risk of QTc prolongation

* Phase 1 study (conducted in the US): : NCT05247970

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New Focus Research Area ：Obstructive Sleep Apnea (OSA)

- **OSA is a QOL disease with high social impact and is at risk of progressing to various diseases**
- **OSA is a disease with high unmet needs as there are no effective pharmacologic treatment options**

Symptoms

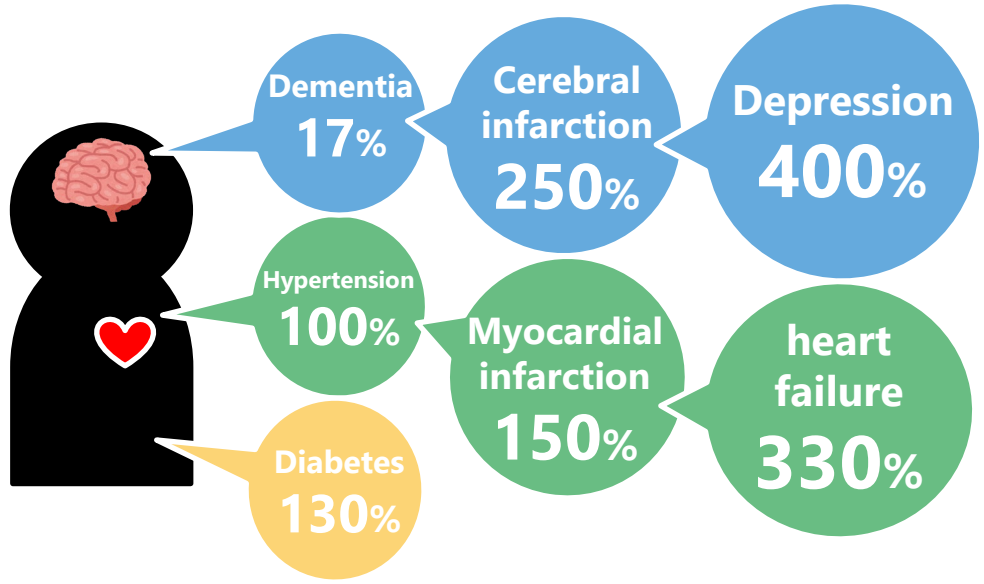
Night time

- Apnea/hypopnea
- Loud snoring
- Frequent urination at night

Day time

- Severe drowsiness
- Fatigue
- Headache upon waking up
- Concentration/memory ability

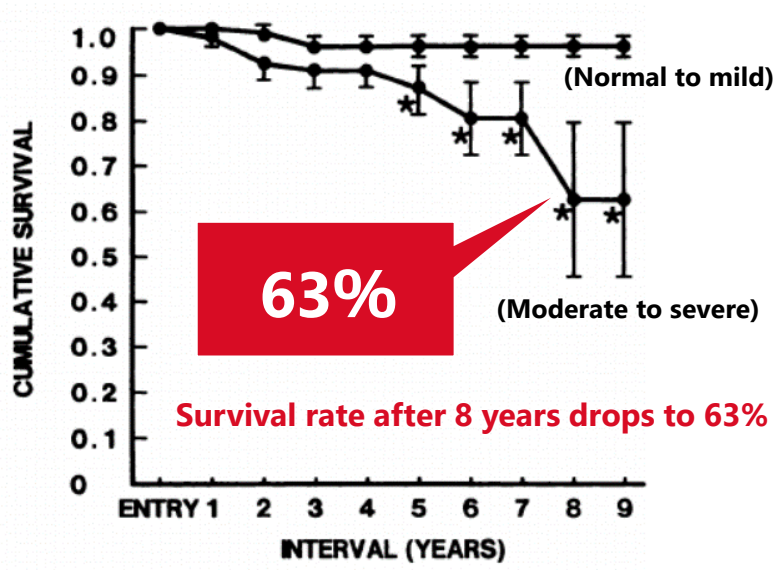
Increased risk of developing various diseases



※ Risk of onset in OSA patients when the risk of onset in healthy individuals is set to 1

Survival rates are significantly reduced

Apnea index and mortality rate of OSA patients



Survival rate after 8 years drops to 63%

DataSource： *Am Rev Respir Dis* (1988) 138(2):337-40, *PharmacoEconomics* (2021) 39:653–665, *J Abnorm Child Psychol* (2019)47(8):1327-1338. *Eur Respir J* (2016) 47(4):1162-1169, *Chest* (1988) 94(1):9-14

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New Focus Research Area：Vision for Drug Discovery for OSA Treatment

We take a multifaceted approach to provide the right treatment options for each patient

Upper airway obstruction

Unstable breathing
(Excessive ventilation response)

OSA pathology is mainly formed by a complex interplay of four factors

Upper airway dilator muscle strength/responsiveness

Unstable sleep
(Decrease ofarousal threshold)

The degree of influence of each factor on OSA varies from patient to patient, resulting in various symptoms

EX) Loud snoring, Severe apnea, Night sweats, Waking up in the middle of the day, Frequent urination, Severe daytime sleepiness, Decreased concentration and memory, Headache upon waking up, Feeling of headache and fatigue

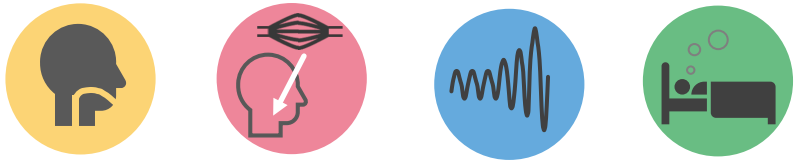
New Focus Research Area : Established *Shionogi-Apnimed Sleep Science, LLC*

Build a system that enables the creation of solutions according to the four main factors of OSA and address to solve social issues

Apnimed

Expertise in OSA

- Robust R&D networks in clinical sites
- Experienced R&D team, especially strength in translational research, expertise in OSA
- Create new treatment combination approaches
  - Possesses multiple new drug candidates (assets) based on pathophysiology



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Strengths in small molecule drugs

- Innovation skills
  - Highly efficient small molecule drug discovery engine
  - High ability to create best-in-class compounds

CRESTOR® rosuvastatin calcium
Tivicay® dolutegravir
xofluza® (baloxavir marboxil) tablets
Fetroja® (cefiderocol) for injection
XOCOVA

Established a Joint Venture Company, which combines the strengths of both companies

Updates on HIV business

SHIONOGI

Progress of HIV Business by ViiV: Update on Medium- to Long-Term Strategy*

The road to sustainable growth of SHIONOGI's HIV business has become clearer

1. 2021-2026 CAGR upgraded to 6% - 8% (from mid single digit %)
2. Outlook for LA formulation market expansion until 2031
   - Treatment: ~30% LA share (Total market size: ~£20bn assumed)
   - PrEP: ~80% LA share (Total market size: £4-5bn assumed)
3. Every 4 months ULA** formulations projected to launch in 2026 (PrEP) and 2027 (treatment)
4. Every 6 months ULA** formulation in 2028-2030 (Treatment and PrEP)
5. Extended IP timeline and shift to long-acting blunts impact of DTG loss of exclusivity
   - Oral two drug regimens: potential to continue until 2030
   - LA portfolio: drives revenue renewal through 2031 and beyond

* Getting ahead of HIV with ViiV Healthcare management (September 28, 2023) ** Ultra Long Acting: ULA

Progress of HIV Business by ViiV: Sustainable Growth Strategy Centered on LA and ULA

Support short- to long-term growth by increasing sales of three growth drivers and launch of ULA

2021-2026

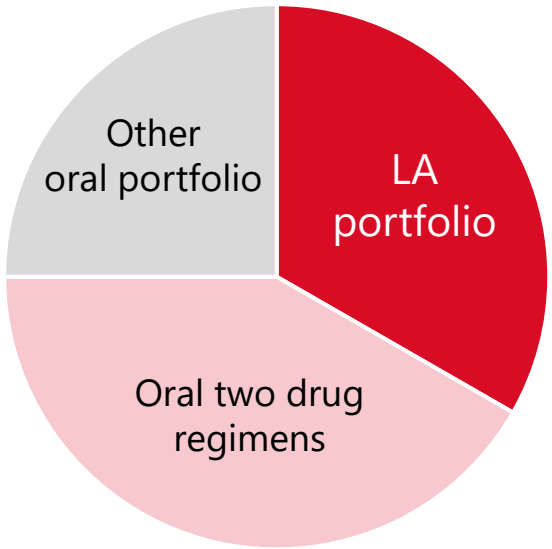
Driving average annual growth rate of **6-8%** for the entire HIV business

- **Cabenuva**
  LA formulation (Treatment)
- **Apretude**
  LA formulation (PrEP)
- **Dovato**
  Oral two drug regimen

2026

Expected sales of **up to £7bn** for the entire HIV business

⇒LA portfolio on track to deliver >£2bn in sales in 2026, representing one-third of overall ViiV HIV sales



2026-2031

Continue to introduce new products that contribute to further QOL improvement

- **ULA (PrEP)**
- **ULA (Treatment)**
- **Self-injection**

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Progress of HIV Business by ViiV: Development of Once Every Four Months Administration Formulation (CAB 400)

Contribute to further QOL improvement by reducing the number of doses per year

- >2x half-life when dosed intramuscularly or subcutaneously, enabling every-four-month (Q4M) dosing with the potential for up to every six-months (Q6M)
- Launched before the dolutegravir patent cliff, further accelerating market penetration of LA portfolio
  - PrEP: 2026
  - Treatment: 2027
- Two options (one to be selected in 2024), aiming for launch in 2027
  - Cabotegravir (CAB 400) + rilpivirine
  - Cabotegravir (CAB 400) + novel bNAb N6LS (VH3810109)
    ⇒Phase IIb clinical trial ongoing
- CAB 400 data to be presented at CROI 2024 (March 3 to 6, 2024)

Progress of HIV Business by ViiV: Main Milestones for Medium- to Long-Term Growth Drivers

Accelerate medium- to long-term growth with integrase inhibitor-based ULA

<table>
<tr><th></th><th>CY2023</th><th>CY2024</th><th>CY2025</th><th>CY2026</th><th>CY2027</th><th>CY2028-2030</th></tr>
<tr><td>ULA
(PrEP)</td><td rowspan="2">Cabotegravir
400mg/ml
dose selection</td><td>Q4M
Registrational
study
start (H1)</td><td></td><td>Q4M
file and launch</td><td>Q6M
Registrational
study
start</td><td>Q6M
file and launch</td></tr>
<tr><td>ULA
(Treatment)</td><td rowspan="2">Q4M
regimen
selection (H2)</td><td rowspan="2">Q4M
Registrational
study start (H2)</td><td></td><td>Q4M
file and launch</td><td rowspan="2">Q6M
file and launch</td></tr>
<tr><td>Self-injection
(Treatment)</td><td></td><td colspan="2">Q6M
regimen selection・Registrational
study start</td></tr>
<tr><td>Self-injection
(Treatment)</td><td></td><td>regimen
selection (H2)</td><td>Device set-up
(H2)</td><td>Registrational
study start</td><td></td><td>file and launch</td></tr>
</table>

Appendix

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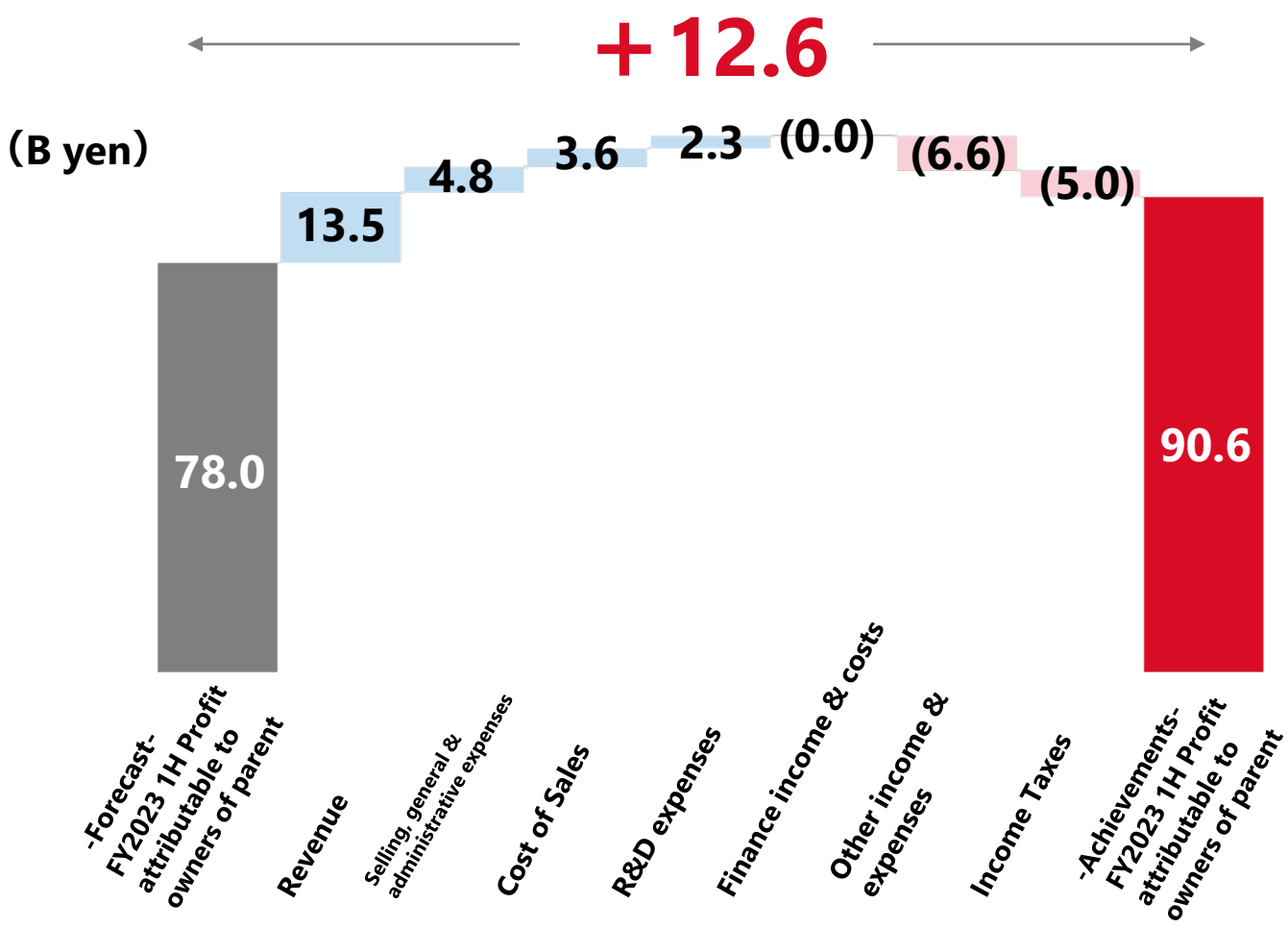
Main Variation Factors of Profit attributable to owners of parent (Forcast Comparison)



Revenue

- Increase：Domestic sales, Overseas subsidiaries /export, Royalty income

Selling, general & administrative expenses

- Decrease：Selling expenses of ensitrelvir in Asia
  ：Delay in IT cost recording and delayed progress in IT investment

Cost of Sales

- Decrease：Approval of ensitrelvir in Asia

Other income & expenses

- Increase：Costs related to implementation of early retirement program

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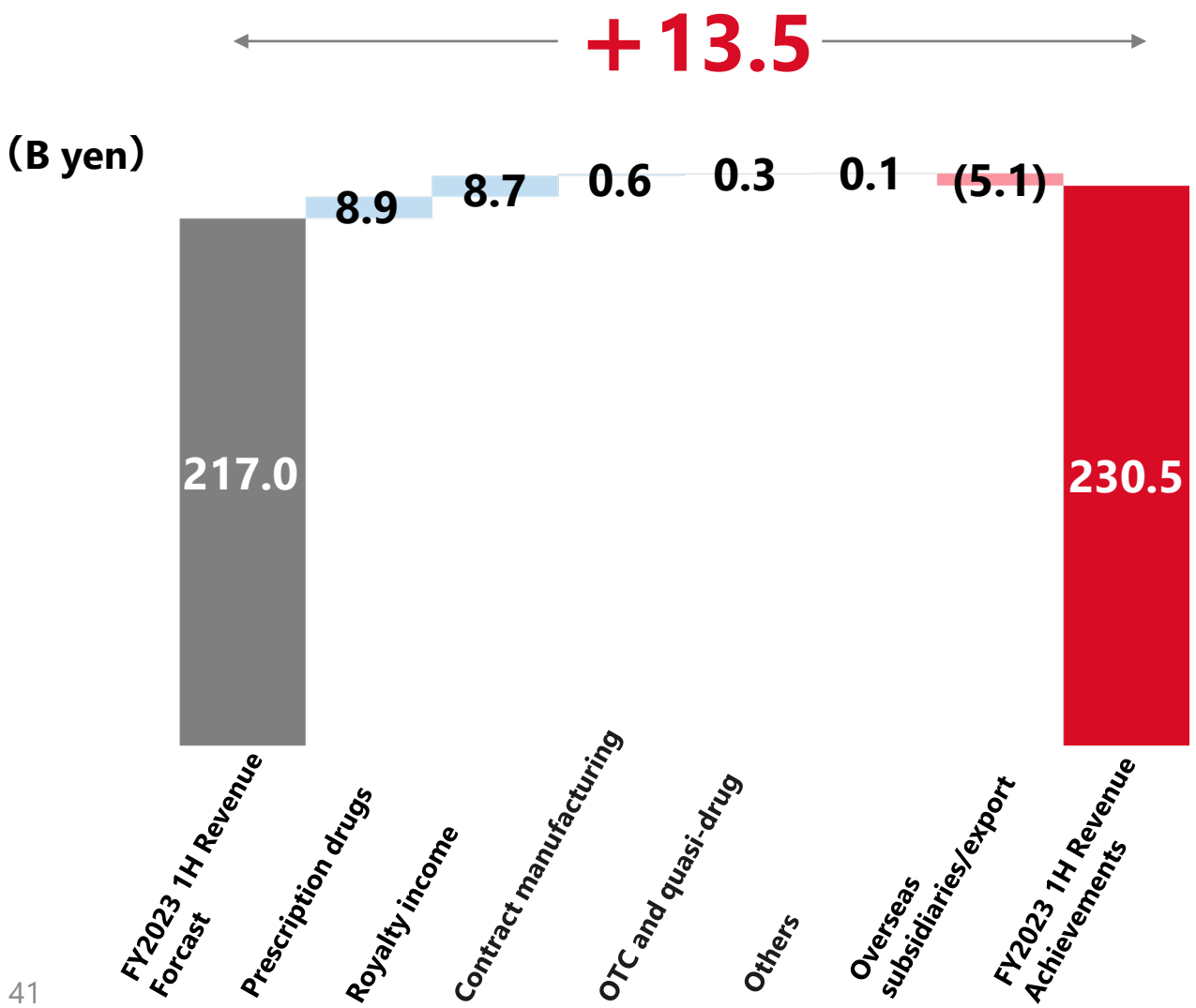
Main Variation Factors of Revenue (Forcast Comparison)



Prescription drugs

- Increase : Sales of Xocova and Xofluza

Royalty income

- Increase: Strong sales of ViiV's HIV franchise

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (Fetroja、Fetcroja)
- Decrease: Approval of ensitrelvir in Asia

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Partial changes to SHIONOGI R&D Day 2022 materials

S-309309：Profile

Indication

- Obesity

Product characteristics

- Best-in-class efficacy among existing oral drugs (weight loss of 10% or more per year) with no safety concern

Market

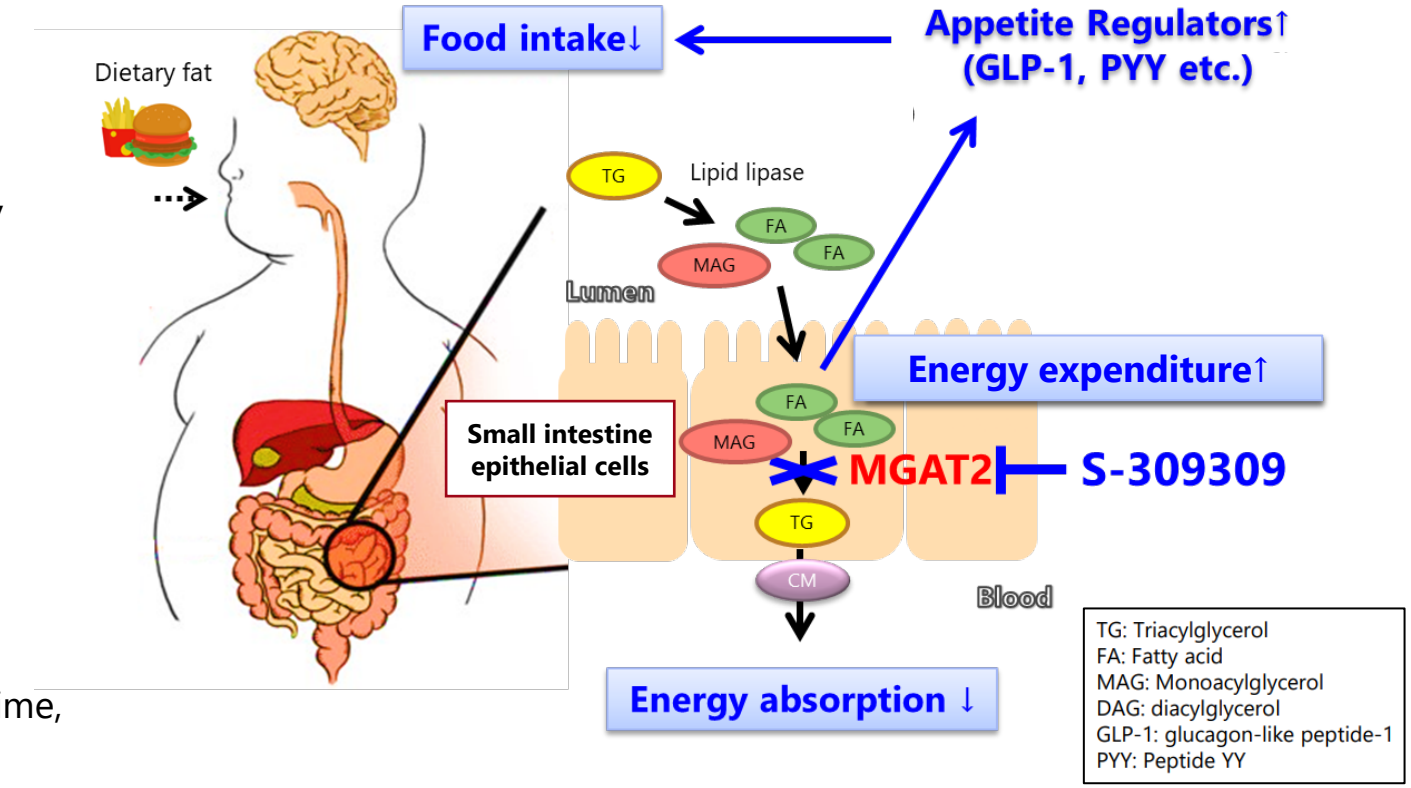
- Obese patients*1：245 million（7MM**）、125 million (U.S.)

Unmet needs

- There is a demand for a drug that has no safety concerns, shows a sufficient weight loss effect over a long period of time, and has a low out-of-pocket cost.

Mechanism of action

- Monoacylglycerol transferase 2 (MGAT2) inhibitor



** 7 major markets; US, France, Germany, Italy, Spain, UK and Japan

S-309309：Trial Overview

Partial changes to SHIONOGI R&D Day 2022 materials and SHIONOGI 2023 1Q Financial results materials

Phase 1 Single dose trial

Country	U.S.
Trial design	Phase 1 (single/multiple), single-center, randomized, double-blind, placebo-controlled trial • Part 1: Single dose (1-300 mg/person): Healthy adults • Part 2: Multiple doses (50, 100 mg/person, 14 days): Healthy adults and obese but otherwise healthy adults
Evaluation content	• Safety and tolerability with single and multiple doses • PK after single and multiple doses • Food effect, QT analysis, Drug-drug interaction (midazolam)
Trial period	January 2022 (FPI) to October 2022 (LPO)

Phase 2 trial

Country	U.S.
Subject	Adults with a BMI of 30 or higher
Trial design	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
Dosage number of cases	• Oral once daily for 24 weeks • S-309309: 3 doses, placebo,80 in each group (320 in total)
Primary endpoint	Percent change in body weight from baseline (week 24)
Secondary endpoint	• Percentage of subjects achieving ≥5%/10%/15%/20% weight loss • Waist circumference, waist/hip ratio, BMI, abdominal fat

Pipeline: Infectious Disease

as of October 30, 2023

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-872600 Influenza nasal vaccine	**S-337395** RSV infections		**Olorofim [F901318]** Invasive Aspergillosis	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-875670 COVID-19 nasal vaccine	**S-892216** COVID-19 treatment		**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Ensitrelvir** COVID-19 prevention	**S-268019*3** COVID-19 Prophylactic vaccine
S-540956 Nucleic acid adjuvant	**S-743229** AMR (Urinary tract infection)		**S-268019** COVID-19 Prophylactic vaccine	**Ensitrelvir** COVID-19 treatment (Ages 5-11)	**Cefiderocol*4** Various infectious diseases
S-554110 Nontuberculous mycobacterial infection				**S-268019** COVID-19 (Ages 5-19)	**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-268023 COVID-19 Prophylactic vaccine (XBB 1.5)					**Baloxavir *5** Influenza virus infection (5-11 years old, treatment and prevention)
S-649228 AMR (Various infectious diseases)					

Change from July 10 to October 30, 2023
S-266023 : Add Code No. S-649228 : Add Code No. S-743229 : Conducting Phase 1

Out license

S-365598 HIV infection	**S -555739 [Asapiprant]** Treatment by suppressing aggravation of COVID-19	**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)	**Baloxavir** Influenza virus infection (Transmission)	**Baloxavir (US)** Influenza virus infection (Pediatric, < 1year old)

: Global development

: Progress from July 31 to October 30, 2023 *,*3 Phase 2/3、Phase 3 ongoing *2 Korea *4 Japan, Taiwan *5 Taiwan

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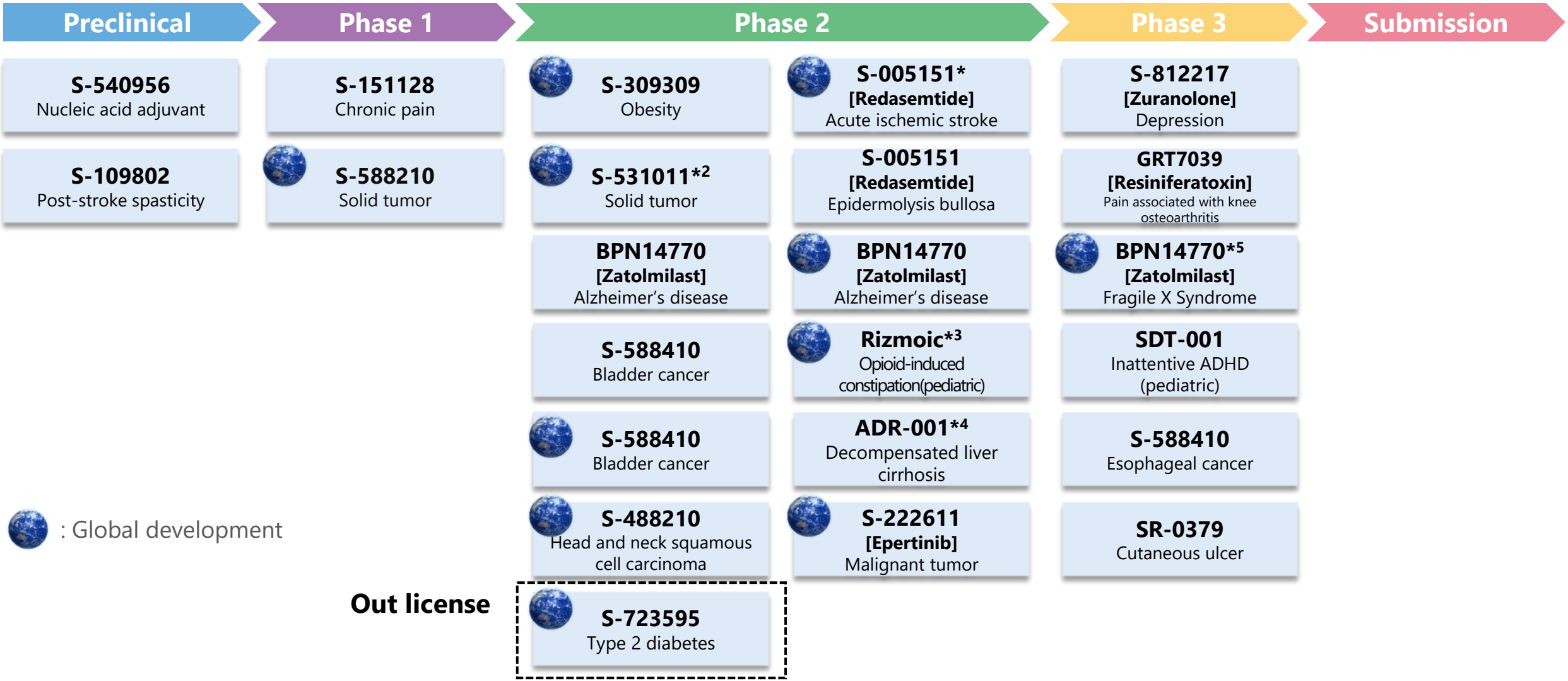
Pipeline: QOL Diseases with High Social Impact

as of October 30, 2023



* Global Phase 2b ongoing *2 Phase 1b/2 ongoing *3,4 Phase 1/2 ongoing *5 Phase 2b/3 ongoing

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Other Major Progress*

- **July**
  - Toward the Establishment of a Supply-Chain System to Secure a Stable Domestic Supply of Antibacterial Drugs －Certification of "Plan for Stable Supply of Antibacterial Substances" by Ministry of Health, Labour and Welfare－
- **August**
  - Flomox Fine Granules for children oral cephem antibiotic agent Launched in China
- **September**
  - Critical agreement paves way for new model to accelerate access to important antibiotics for serious bacterial infections
  - Regarding the Adoption of Public Offering for "the Project that Establish Biopharmaceutical Manufacturing Bases to Strengthen Vaccine Production Structure" Led by the Ministry of Economy, Trade and Industry- Establishing domestic vaccine manufacturing for future pandemics –
  - Expansion of "Gamma Wave Sound" initiative by Shionogi & Co., Ltd., Shionogi Healthcare, and Pixie Dust Technologies to fight dementia with sound
- **October**
  - Research results and efforts related to malaria are introduced in Nature magazine's Nature Outlook Malaria special feature
  - Holding a Sustainability Meeting
  - Taiwan Shionogi signs Xofluza stockpiling agreement with Taiwan CDC

* Progress from July 31, 2023 to October 30, 2023

Forward-Looking Statements

- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
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- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials, and failure to gain market acceptance.
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