

# 1<sup>st</sup> Half of Fiscal 2023 Financial Results

October 31, 2023

Shionogi & Co., Ltd.



SHIONOGI

# Agenda

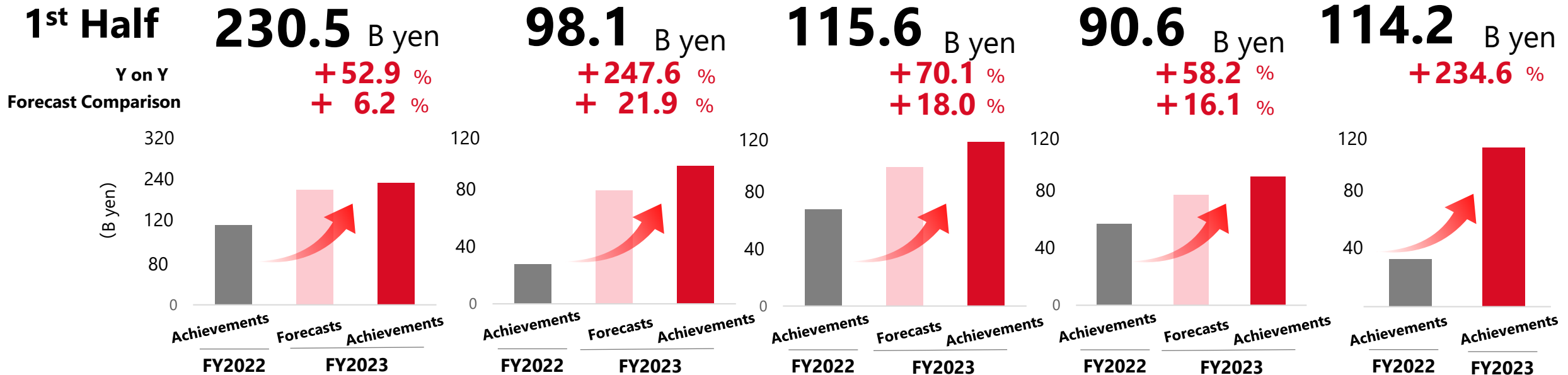
- **Overview of 1<sup>st</sup> Half FY2023 Financial Results (P.3-12)**
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- **Shareholder Return (P.19-20)**
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# **Overview of 1<sup>st</sup> Half FY2023 Financial Results**

# 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*
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\* 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.)

# 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)

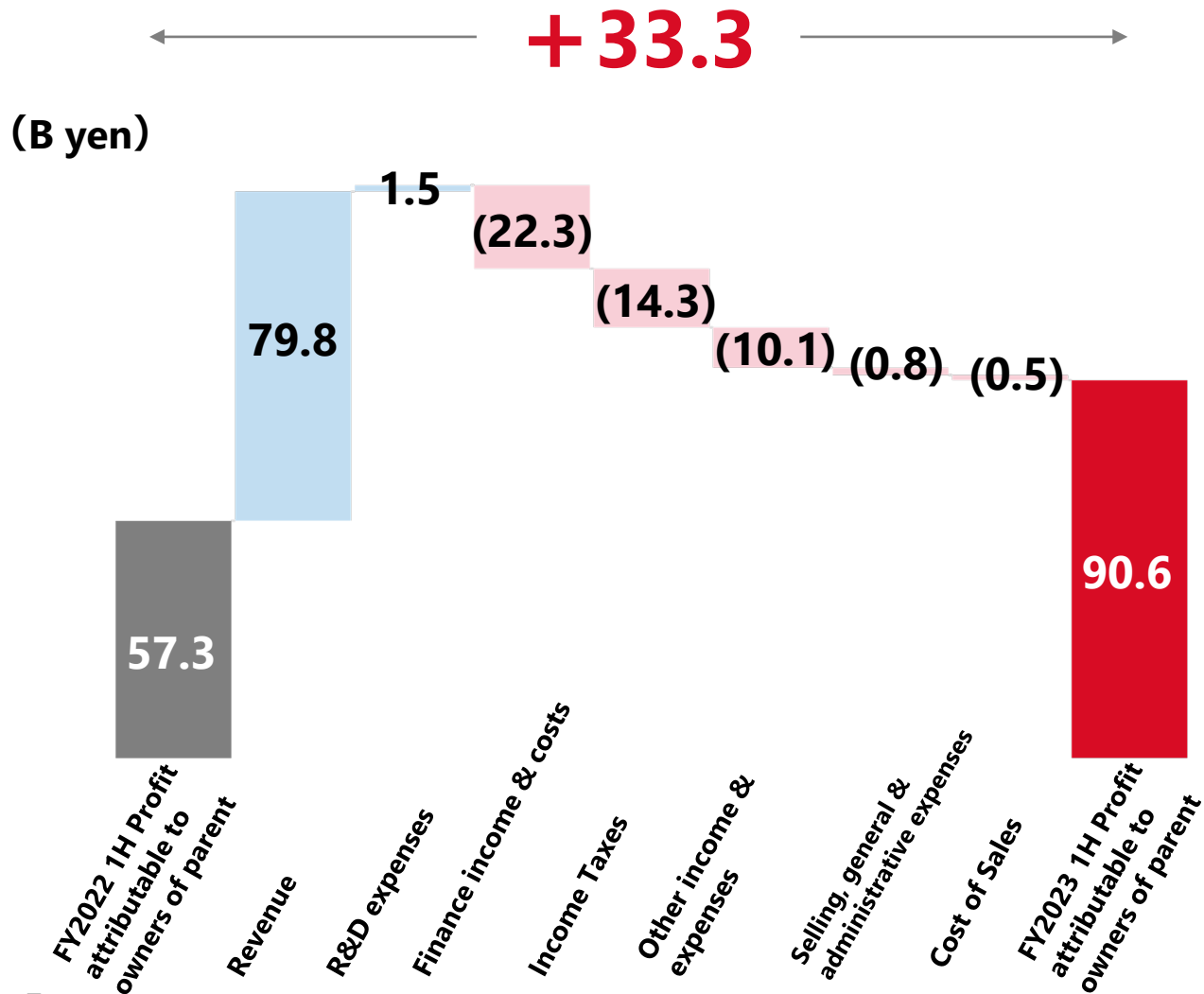
	FY2023 Forecasts	FY2023 1H Results
USD(\$) <span> </span> – JPY(¥)	130	141.06
GBP(£) <span> </span> – JPY(¥)	160	177.63
EUR(€) <span> </span> – JPY(¥)	140	153.46

# 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	14.5	12.1		18.2			
	69.0	31.5	27.9	88.5	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	47.7	41.8		64.5			
	229.0	103.5	96.5	93.2	97.2	(0.8)	(0.7)	
Selling, general & administrative expenses	28.9	24.9	21.4		32.1			
	130.0	54.0	49.2	91.2	48.5	1.6	0.8	
R&D expenses	22.0	22.8	20.5		32.3			
	99.0	49.5	47.2	95.4	48.7	(3.1)	(1.5)	
Other income & expenses	(2.0)	(1.5)	(8.1)	-	2.0	-	(10.1)	
Operating profit	33.3	37.1	42.6		18.7			
	150.0	80.5	98.1	121.9	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	45.2	50.1		45.1			
	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	

# 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

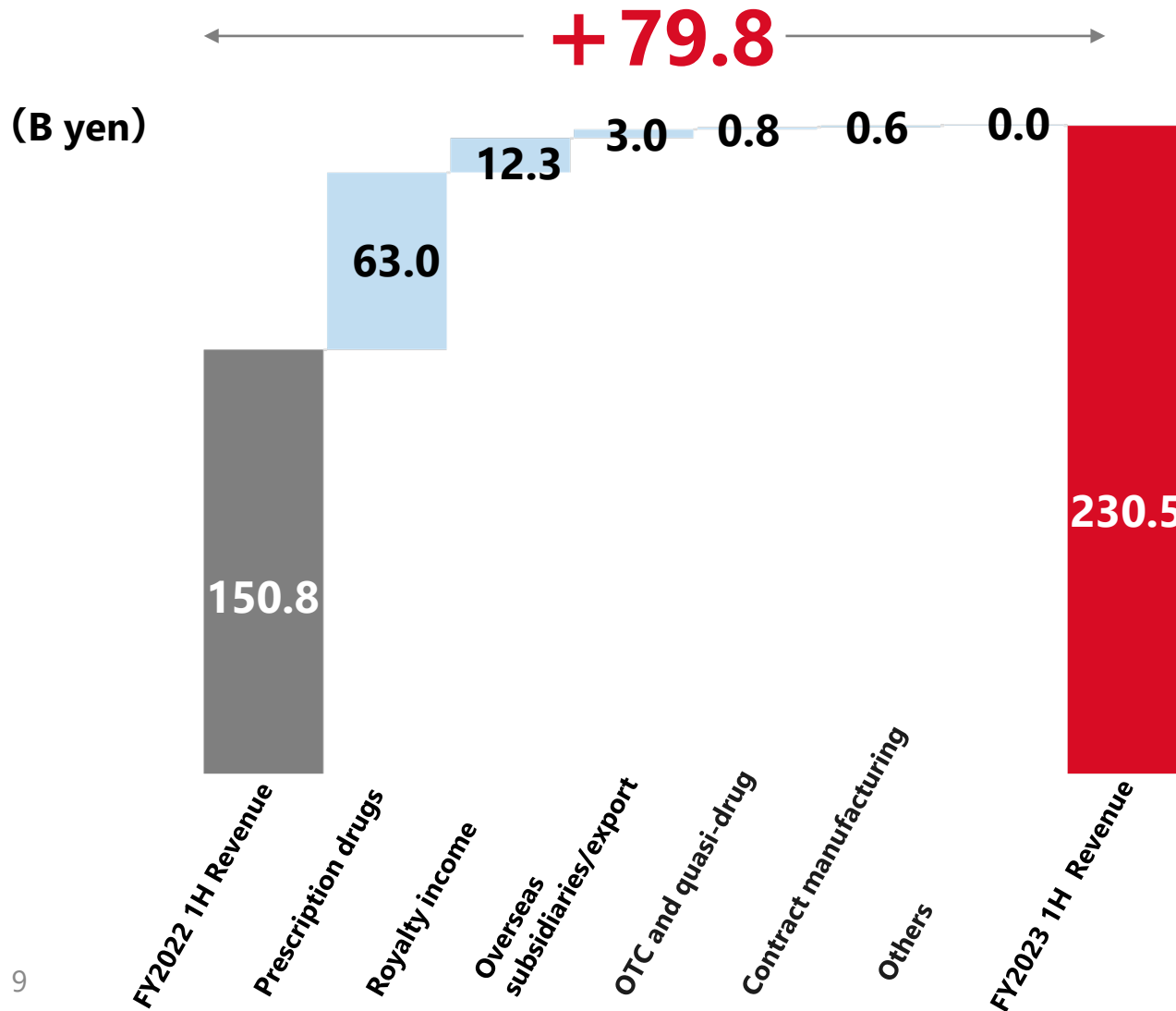
# Revenue by Segment

(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、Fetroja)
- Decrease: Change in Osphena sales scheme

# 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

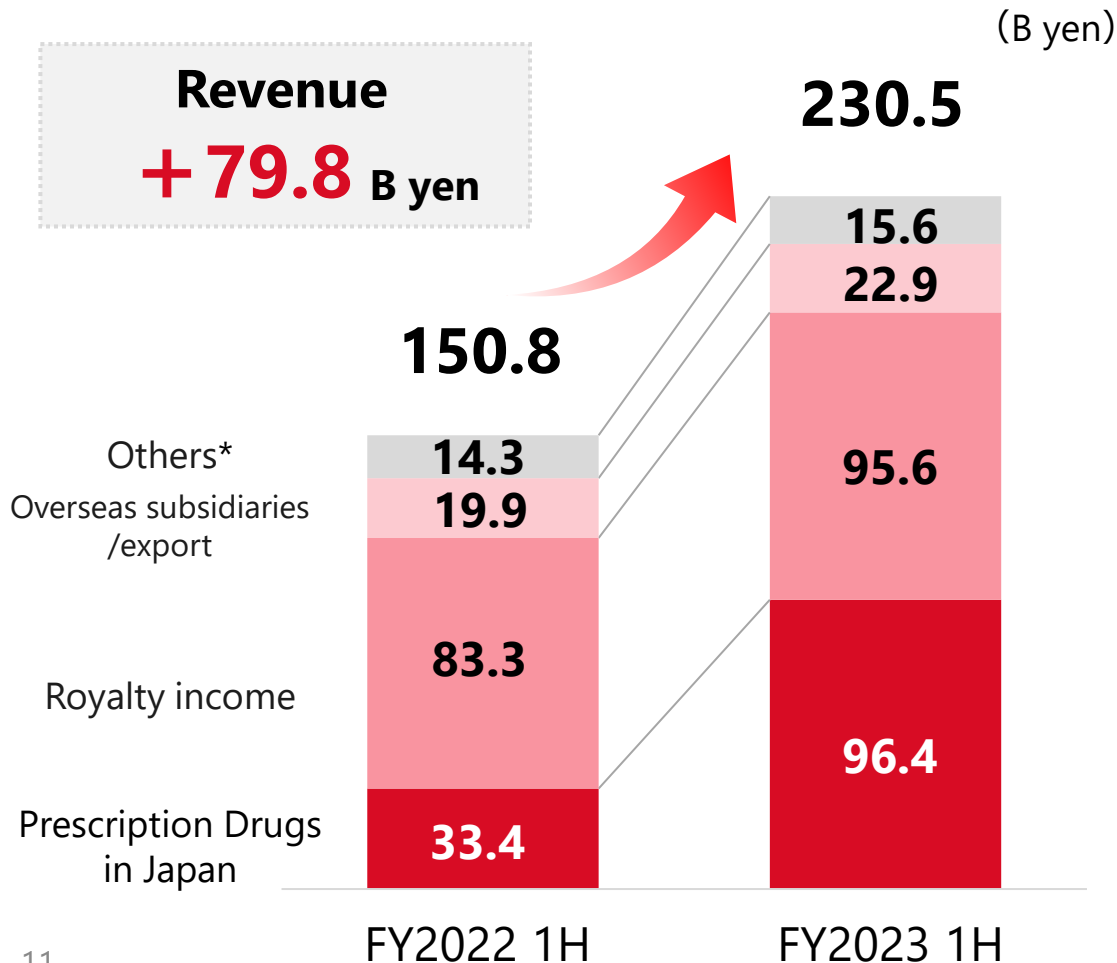
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE

\* Returns of Xofluza and Rapiacta

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

# 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

# 1<sup>st</sup> 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 1<sup>st</sup> Half FY2023 Financial Results**

# 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	13.2		16.1	14.4		14.6		
	69.0	59.5	(9.5)	37.5	31.6	(5.9)	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	51.3		53.9	61.3		47.8		
	229.0	231.0	2.0	125.5	134.5	9.0	203.9	13.3	27.1
Selling, general & administrative expenses	28.9	26.4		32.6	31.8		23.8		
	130.0	119.0	(11.0)	76.0	69.8	(6.2)	101.5	17.2	17.5
R&D expenses	22.0	24.9		21.2	29.5		24.0		
	99.0	112.0	13.0	49.5	64.8	15.3	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	33.3		29.8	23.6		34.9		
	150.0	150.0	-	69.5	51.9	(17.6)	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	42.8		40.6	35.0		51.6		
	192.5	192.5	-	94.5	76.9	(17.6)	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
Fetroja	-	-	-	-	-	-	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
<b>Infectious disease drugs</b>	65.7	<b>97.5</b>	<b>31.8</b>	25.7	<b>48.5</b>	<b>22.8</b>	112.1	(13.0)	(14.6)
COVID-19 related products + Influenza franchise	57.3	<b>88.6</b>	<b>31.3</b>	21.5	<b>44.2</b>	<b>22.7</b>	103.6	(14.5)	(15.0)
<b>Cymbalta</b>	4.2	<b>4.2</b>	-	2.0	<b>2.1</b>	<b>0.0</b>	5.4	(23.5)	(1.3)
<b>OxyContin franchise</b>	4.1	<b>4.3</b>	<b>0.1</b>	2.0	<b>2.1</b>	<b>0.1</b>	4.4	(3.5)	(0.2)
<b>Symproic</b>	4.9	<b>4.9</b>	-	2.7	<b>2.8</b>	<b>0.2</b>	3.4	44.6	1.5
<b>Actair</b>	1.0	<b>1.0</b>	-	0.6	<b>0.7</b>	<b>0.1</b>	0.5	91.0	0.5
<b>Mulpleta</b>	0.1	<b>0.1</b>	-	0.1	<b>0.1</b>	<b>0.0</b>	0.1	25.9	0.0
<b>Pirespa</b>	1.9	<b>1.9</b>	-	0.9	<b>0.9</b>	<b>0.0</b>	2.5	(24.4)	(0.6)
<b>Others</b>	52.1	<b>53.1</b>	<b>1.0</b>	12.8	<b>13.5</b>	<b>0.8</b>	30.6	73.6	22.5
ADHD drug (Intuniv and Vyvanse)**	25.0	<b>25.0</b>	-	-	-	-	20.6	21.4	4.4
<b>Prescription drugs</b>	134.1	<b>167.0</b>	<b>32.9</b>	46.7	<b>70.6</b>	<b>24.0</b>	179.7	(7.1)	(12.7)

COVID-19 related products

- Xocova
- COVID-19 vaccines

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu•Neo

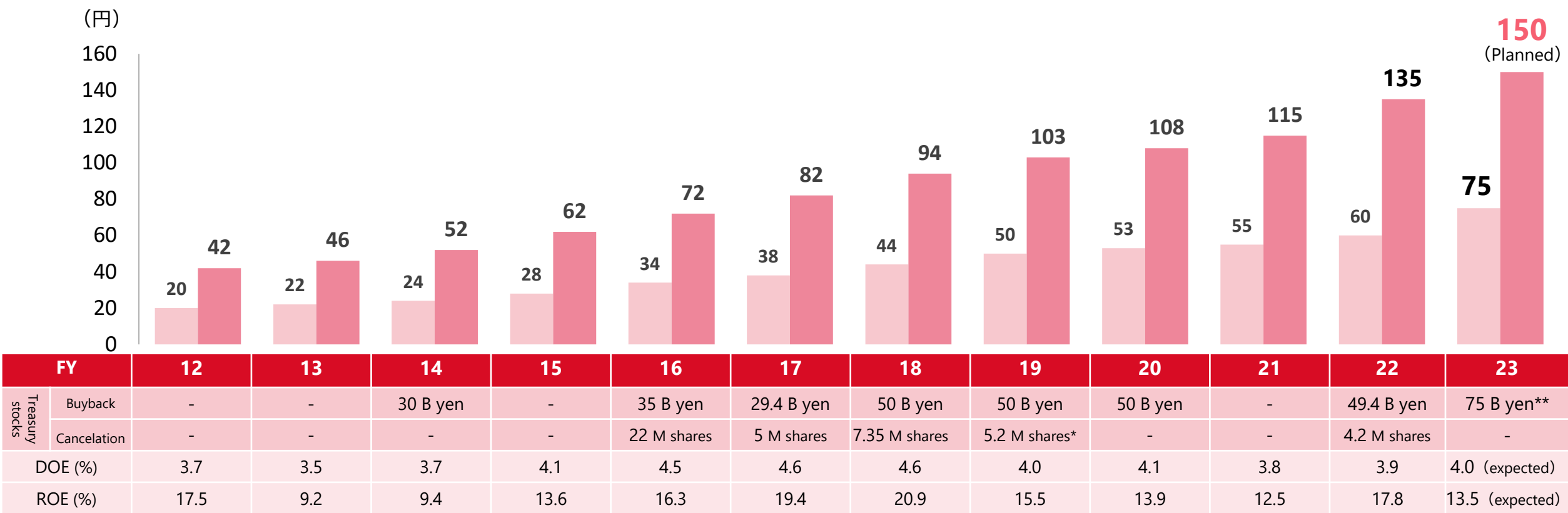
Infectious disease drugs

- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE

# Shareholder Return

# 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 12<sup>th</sup> consecutive year in FY2023



# Updates on COVID-19 Treatment

# Xocova: Development Plan

## Promoting development that meets medical and social needs

<b>SCORPIO-HR trial*</b>	<p><b>Purpose: Verify the effectiveness of improving clinical symptoms in outpatient COVID-19 cases, including patients at risk of developing severe illness</b></p> <ul style="list-style-type: none"><li>• Target number of the enrollment : 2,000 cases</li><li>• The completion of enrollment will be expected by the end of this year</li><li>• Discussions with FDA regarding efficacy verification against Long COVID</li></ul>
<b>SCORPIO-PEP trial</b>	<p><b>Purpose: Verify the effectiveness of suppressing the onset of COVID-19 symptoms in close contacts</b></p> <ul style="list-style-type: none"><li>• Target number of the enrollment: 2,200 cases</li><li>• The enrollment progressing smoothly</li></ul>
<b>Pediatric trial</b>	<p><b>Purpose: Expand indication to children with limited treatment options</b></p> <ul style="list-style-type: none"><li>• Under 6-12 years old: Clinical trials underway in Japan</li><li>• In parallel, we are preparing a global pediatric trial</li></ul>
<b>STRIVE trial*</b>	<p><b>Purpose: Verification of the efficacy and safety of ensitrevir in hospitalized critically ill patients</b></p> <ul style="list-style-type: none"><li>• Target number of the enrollment: 1,500 cases</li></ul>

# 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

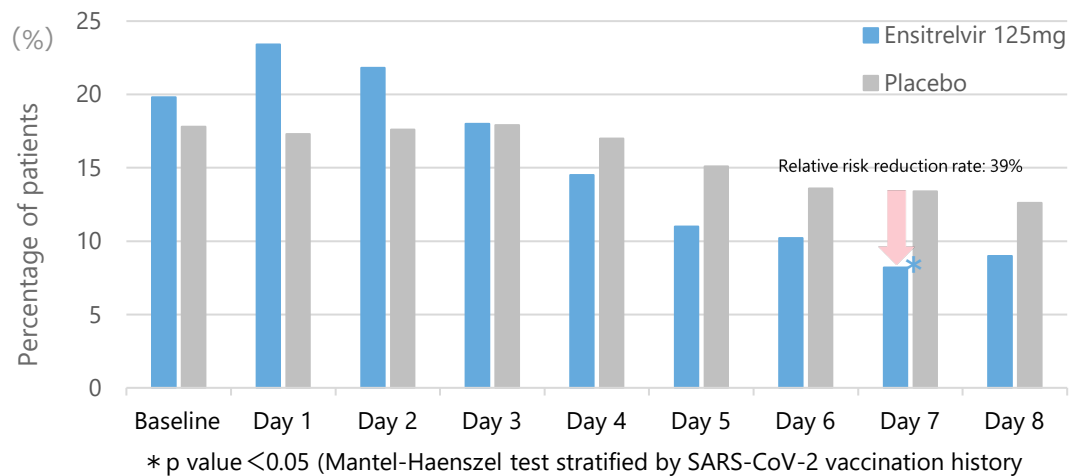
It is a characteristic symptom of COVID-19, and the period of illness tends to be longer than other symptoms

Nature Medicine, 2022; 28, 1031-1041

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

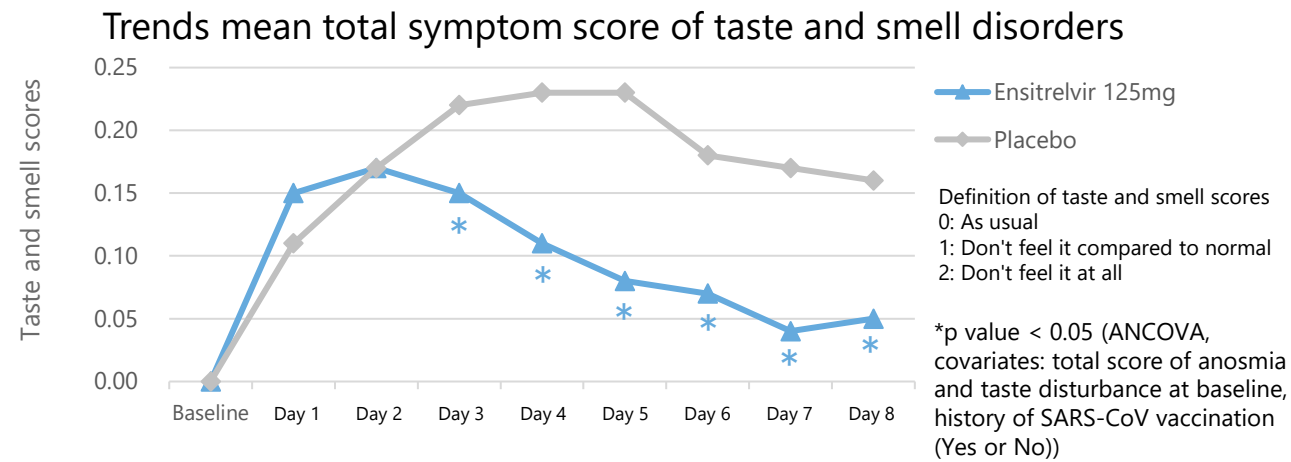
### Percentage of patients with symptoms of taste or smell disorders

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



### 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



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



# **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		

# 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](https://clinicaltrials.gov/ct2/show/study/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  $\beta$ -lactamase inhibitor xeruborbactam with  $\beta$ -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

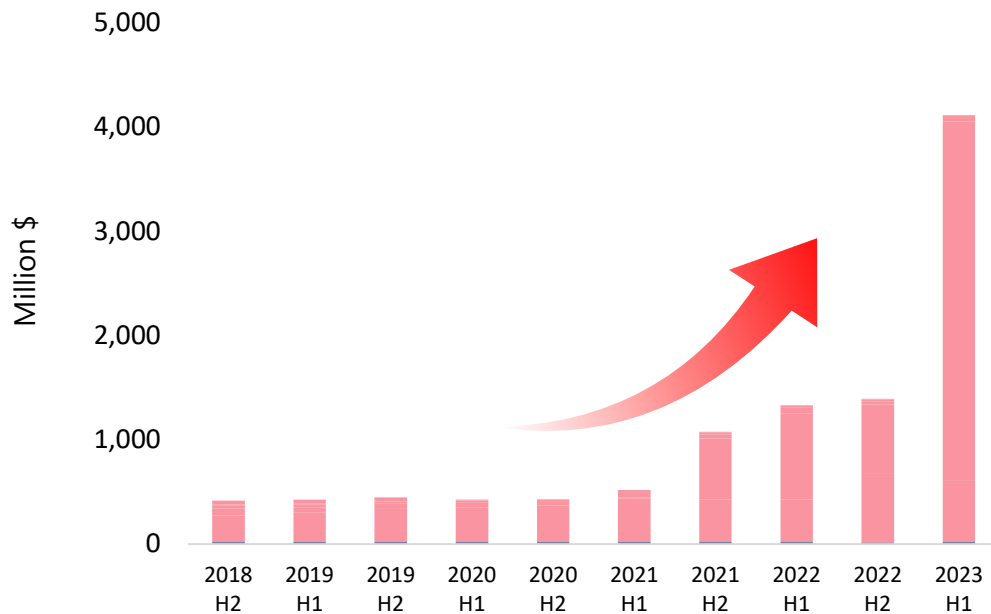
	MIC <sub>90</sub> *3	
	ESBL*4 (N=515)	CRE*5 (N=292)
Meropenem (IV)	0.06	>64
+Xeruborbactam	≤0.03	0.06
Cefepime (IV)	>64	>64
+Xeruborbactam	≤0.03	0.25
Ceftibuten (oral)	>64	>64
+Xeruborbactam	≤0.03	0.06

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

# 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

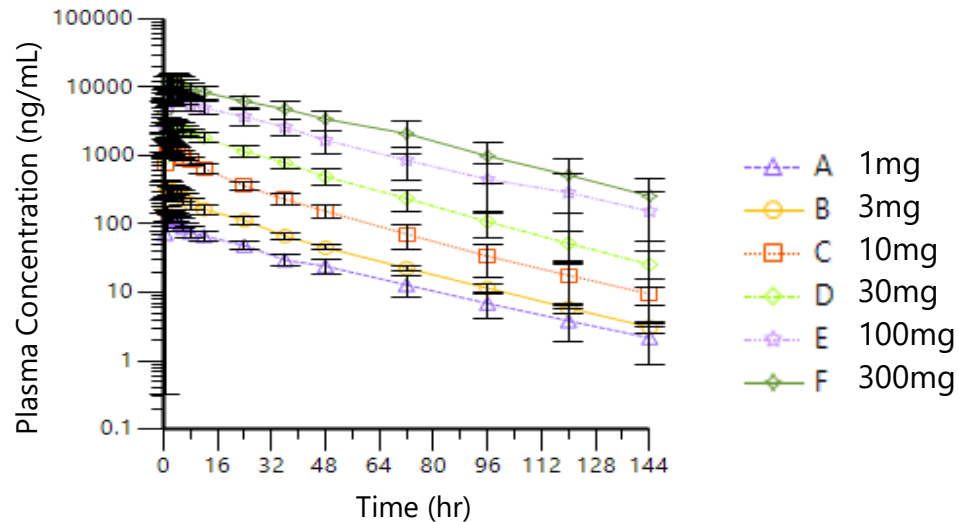
## Differentiating points of S-309309 (MGAT2\* inhibitor)

- **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  $\beta$ -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)

# 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 C<sub>max</sub>/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](https://clinicaltrials.gov/ct2/show/study/NCT05247970)

# Updates on HIV business

# 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



# 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**

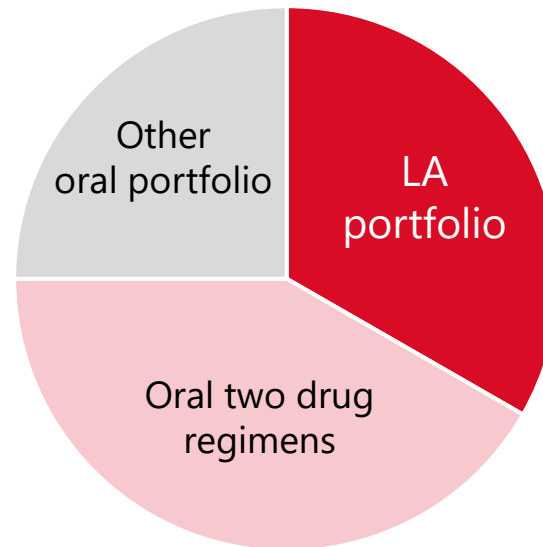
LA formulation  
(PrEP)

**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**

# 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)

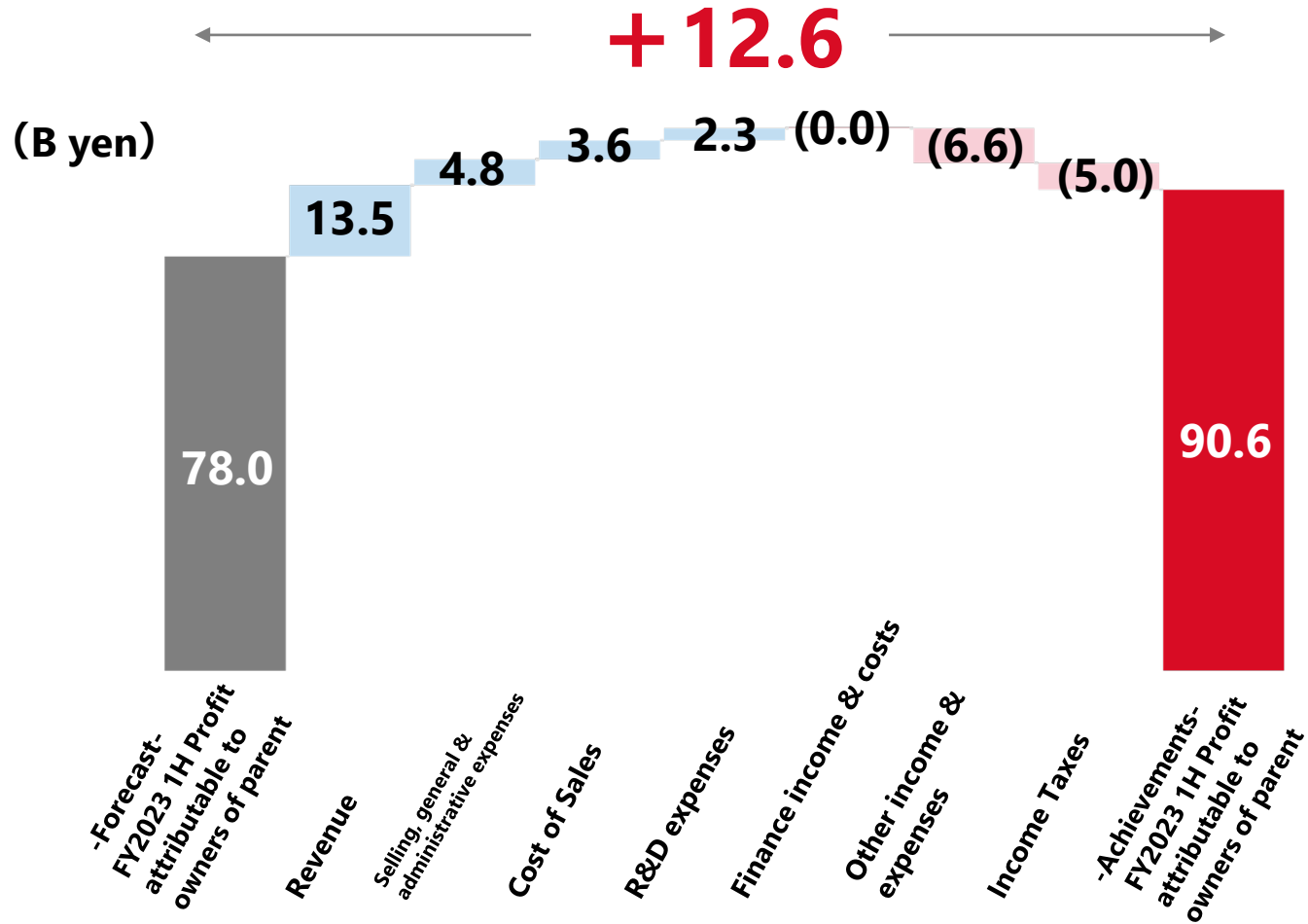
# Progress of HIV Business by ViiV: Main Milestones for Medium- to Long-Term Growth Drivers

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

	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028-2030
ULA (PrEP)	Cabotegravir 400mg/ml dose selection	Q4M Registrational study start (H1)		Q4M file and launch	Q6M Registrational study start	Q6M file and launch
ULA (Treatment)		Q4M regimen selection (H2)	Q4M Registrational study start (H2)		Q4M file and launch	Q6M file and launch
				Q6M regimen selection • Registrational study start		
Self-injection (Treatment)		regimen selection (H2)	Device set-up (H2)	Registrational study start		file and launch

# Appendix

# Main Variation Factors of Profit attributable to owners of parent (Forecast 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

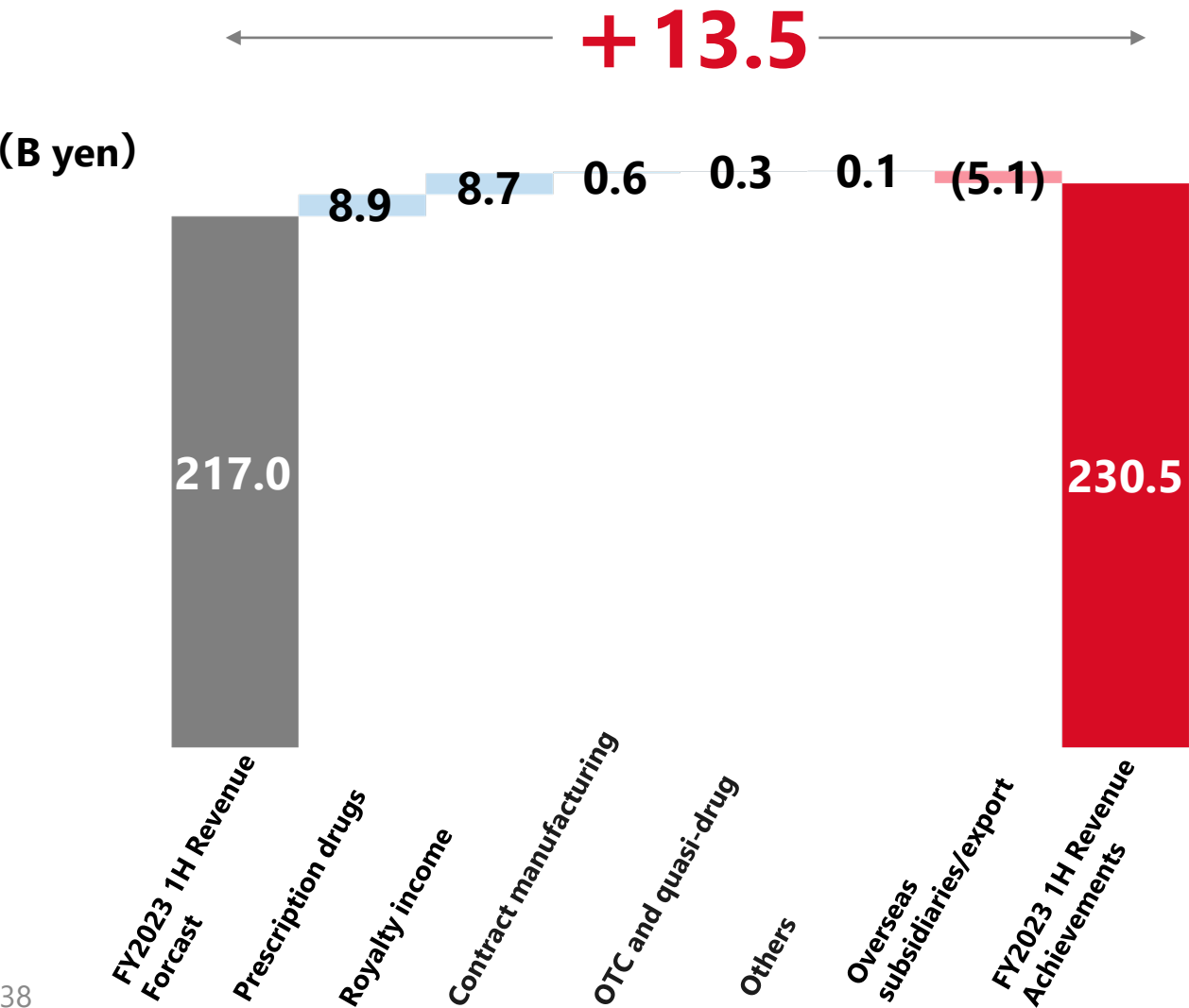
## Cost of Sales

- Decrease : Approval of ensitrelvir in Asia

## Other income & expenses

- Increase : Costs related to implementation of early retirement program

# Main Variation Factors of Revenue (Forecast 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、Fetroja)
- Decrease: Approval of ensitrelvir in Asia

# 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

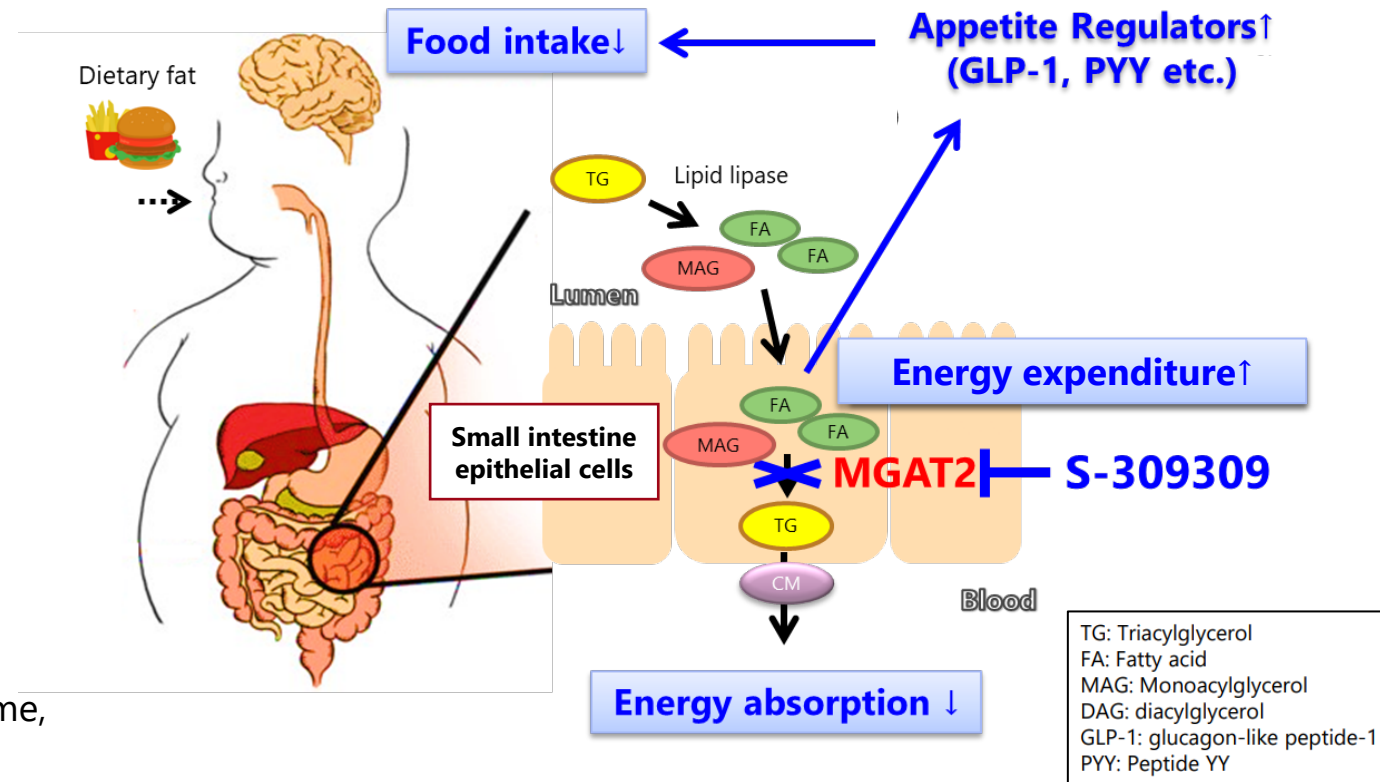
- Obese patients\*<sup>1</sup> : 245 million (7MM\*\*) 、 125 million (U.S.)

## 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



# 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

<b>Country</b>	U.S.
<b>Trial design</b>	Phase 1 (single/multiple), single-center, randomized, double-blind, placebo-controlled trial <ul style="list-style-type: none"><li>• Part 1: Single dose (1-300 mg/person): Healthy adults</li><li>• Part 2: Multiple doses (50, 100 mg/person, 14 days): Healthy adults and obese but otherwise healthy adults</li></ul>
<b>Evaluation content</b>	<ul style="list-style-type: none"><li>• Safety and tolerability with single and multiple doses</li><li>• PK after single and multiple doses</li><li>• Food effect, QT analysis, Drug-drug interaction (midazolam)</li></ul>
<b>Trial period</b>	January 2022 (FPI) to October 2022 (LPO)

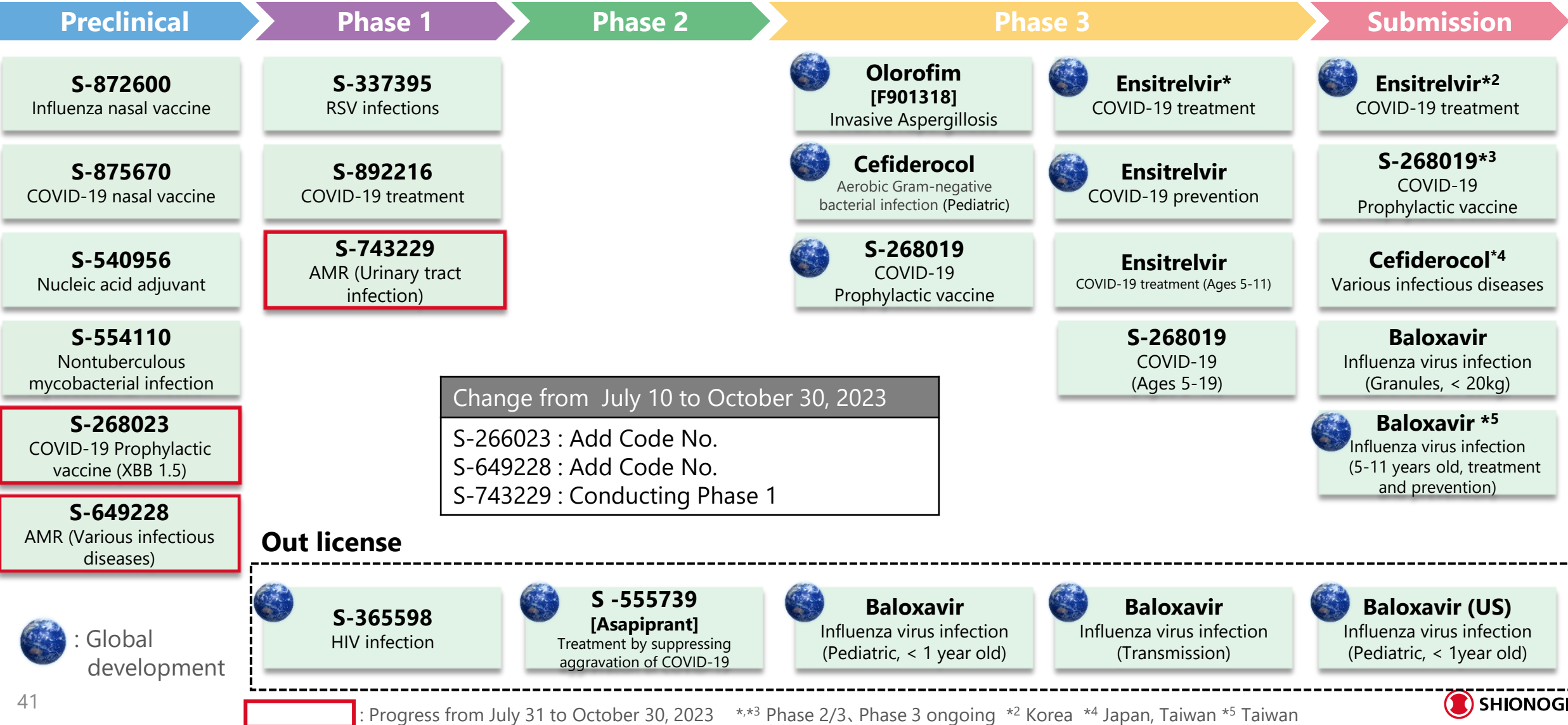
## Phase 2 trial

<b>Country</b>	U.S.
<b>Subject</b>	Adults with a BMI of 30 or higher
<b>Trial design</b>	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
<b>Dosage number of cases</b>	<ul style="list-style-type: none"><li>• Oral once daily for 24 weeks</li><li>• S-309309: 3 doses, placebo, 80 in each group (320 in total)</li></ul>
<b>Primary endpoint</b>	Percent change in body weight from baseline (week 24)
<b>Secondary endpoint</b>	<ul style="list-style-type: none"><li>• Percentage of subjects achieving <math>\geq 5\%/10\%/15\%/20\%</math> weight loss</li><li>• Waist circumference, waist/hip ratio, BMI, abdominal fat</li></ul>



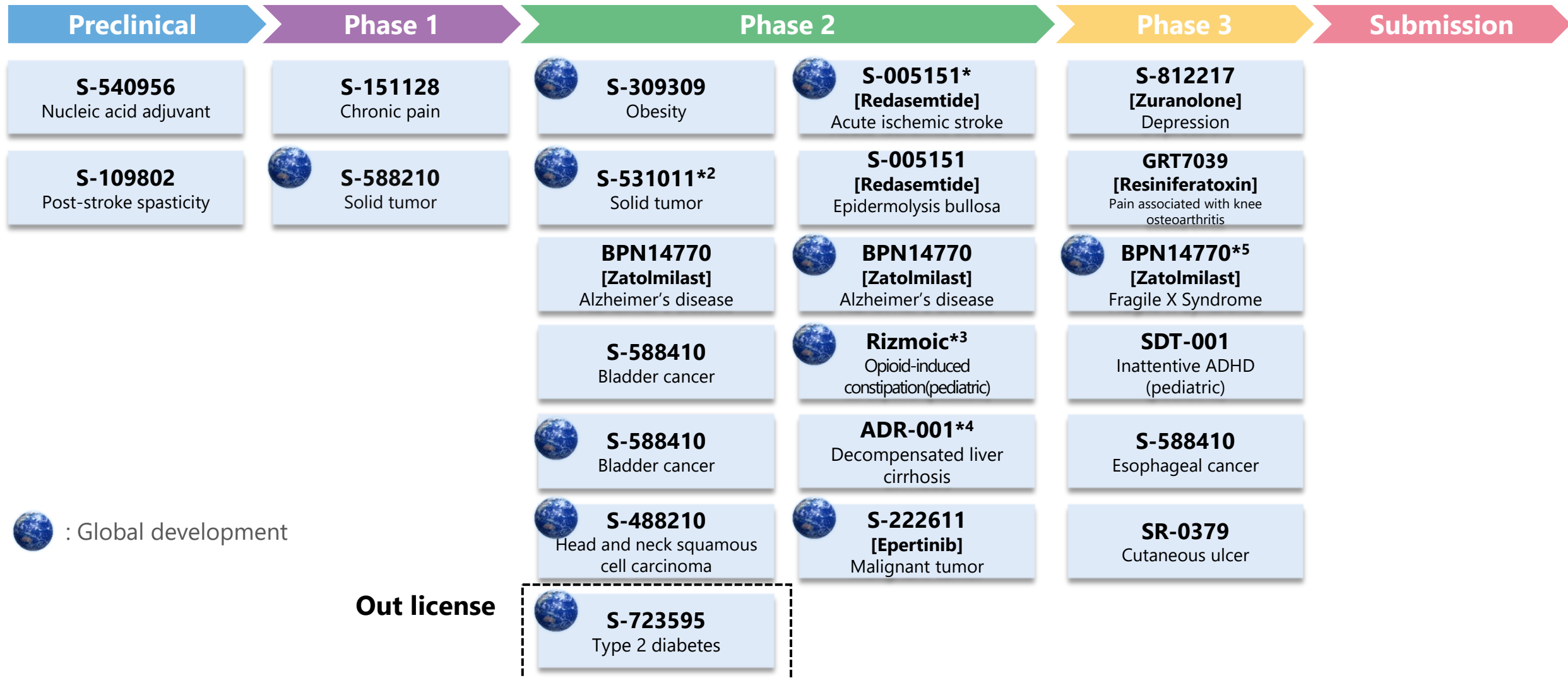
# Pipeline: Infectious Disease

as of October 30, 2023



# Pipeline: QOL Diseases with High Social Impact

as of October 30, 2023



# 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

# 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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