

SMBC Nikko Web IR for Retail Investors

SHIONOGI's Solution of Social Issues and Increase in Corporate Value

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March 4, 2022



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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- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
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- This English presentation was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

1. **Pharmaceutical Business**

- Japanese Pharmaceutical Market
- Challenges and Prospects for the Pharmaceutical Business

2. **What's SHIONOGI**

3. **Sustainable Growth as a Leading Company in Infectious Diseases**

-Aiming to Protect People Worldwide from the Threat of Infectious Diseases-

4. **Shareholder Return**



1. Pharmaceutical Business

– Japanese Pharmaceutical Market

– Challenges and Prospects for the Pharmaceutical Business

Classification of Drugs

- Drugs are generally classified into *prescription drugs* and *OTC* and quasi-drugs*
- Prescription drugs are further classified into *New Prescription drugs* and *generic drugs*

Prescription drugs

Received at a pharmacy after examination by a doctor at a hospital, etc.

New Prescription drugs
"Unmet medical needs"

Generic drugs
"Reduction in social security payments"

OTC and quasi-drugs

Can be purchased without medical prescriptions

"Self-medication"

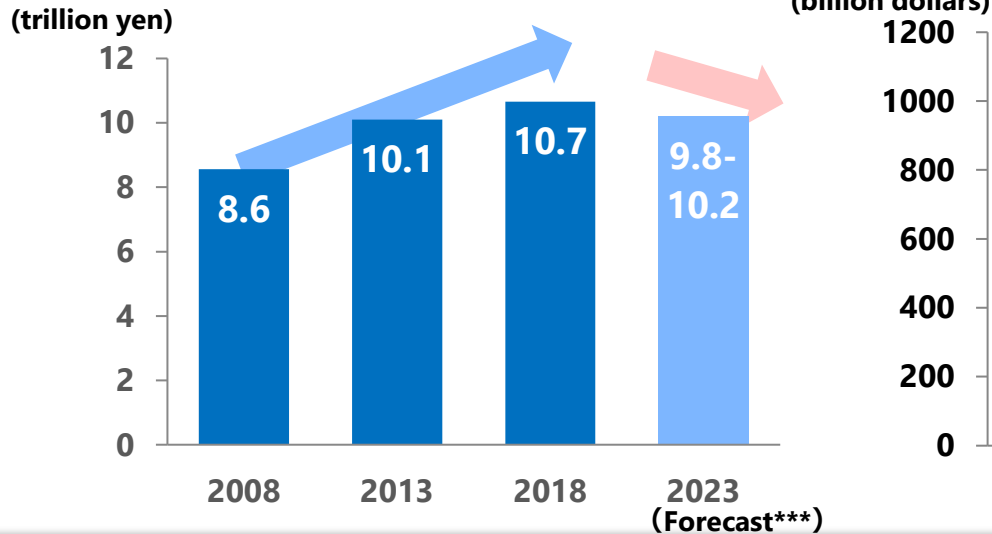


Changes in the Pharmaceutical Market Size

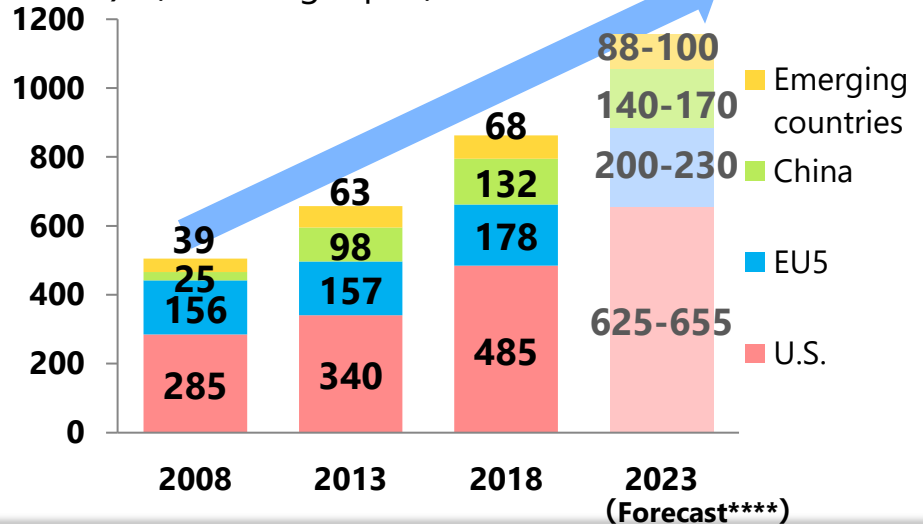


- The Japanese pharmaceutical market is worth **around 10 trillion yen/year**
- Among developed countries, **only the Japanese market is forecast to post negative growth in 2023**
- The global pharmaceutical market, mainly the U.S. and China, is expected to expand

The Japanese pharmaceutical market*



The global pharmaceutical market** (excluding Japan)



1. Pharmaceutical Business

– Japanese Pharmaceutical Market

– Challenges and Prospects for the Pharmaceutical Business

Process to Launch New Prescription Drugs



9 - 16 years

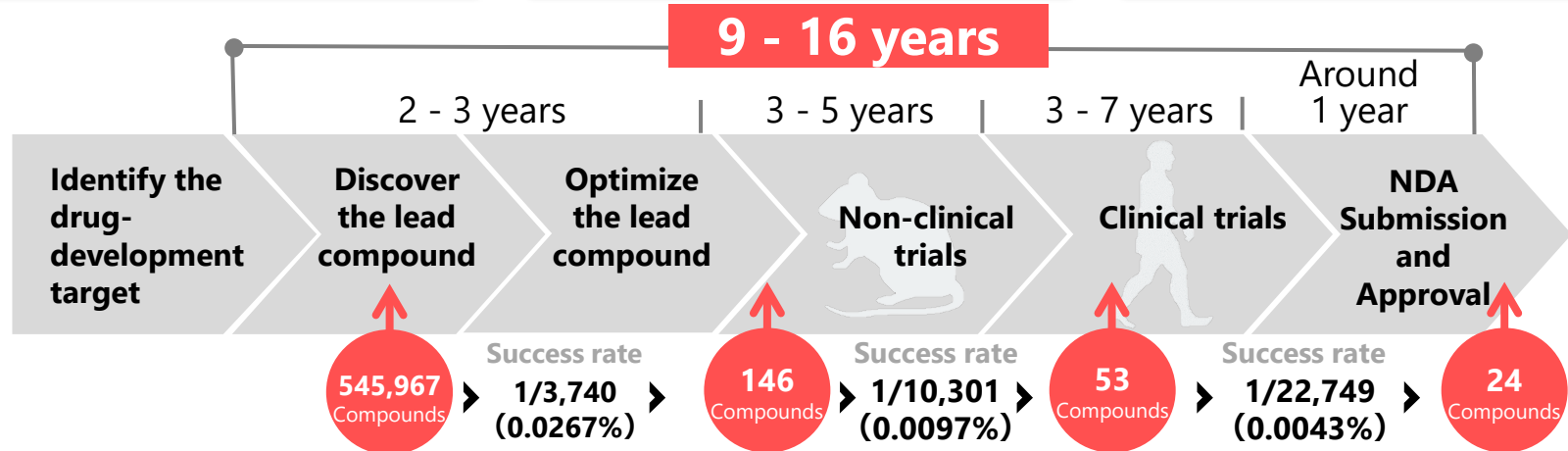
It takes about 15 years from initiation of discovery to launch of a new prescription drug

Tens of billions of yen

Tens of billions of yen to hundreds of billions of yen of R&D expenses are necessary to discover and develop a new prescription drug

0.004%

The probability of a compound being launched as a new drug is about 1 in 23,000



According to a report from Tufts University (US), the development cost required to launch a new drug is approximately 170 billion yen*

Patent Term and Generic Drugs

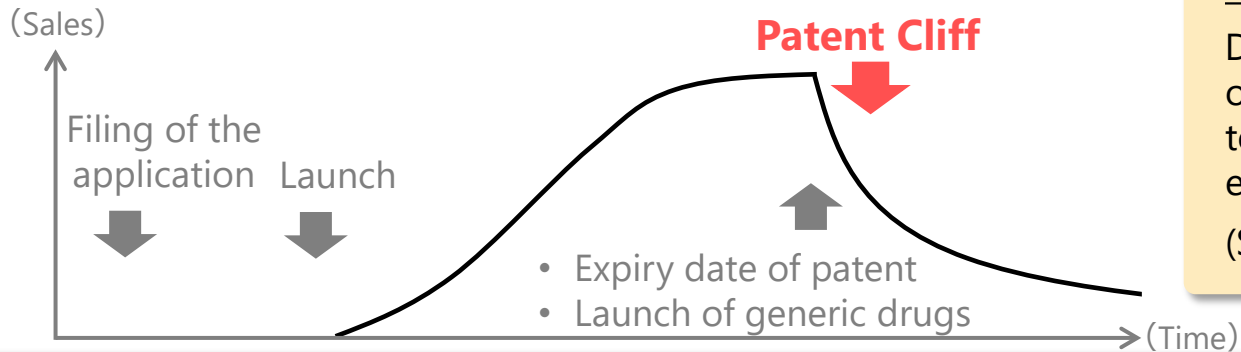
Patent Term is twenty years from the filing date of the application

Patent expiration

Other companies can manufacture the same drug

Generic drugs are launched

Sales in the drug life cycle (Image)



Patent Cliff

Dramatic decrease in the sales of new prescription drugs due to launch of generic drugs after expiry date of patent

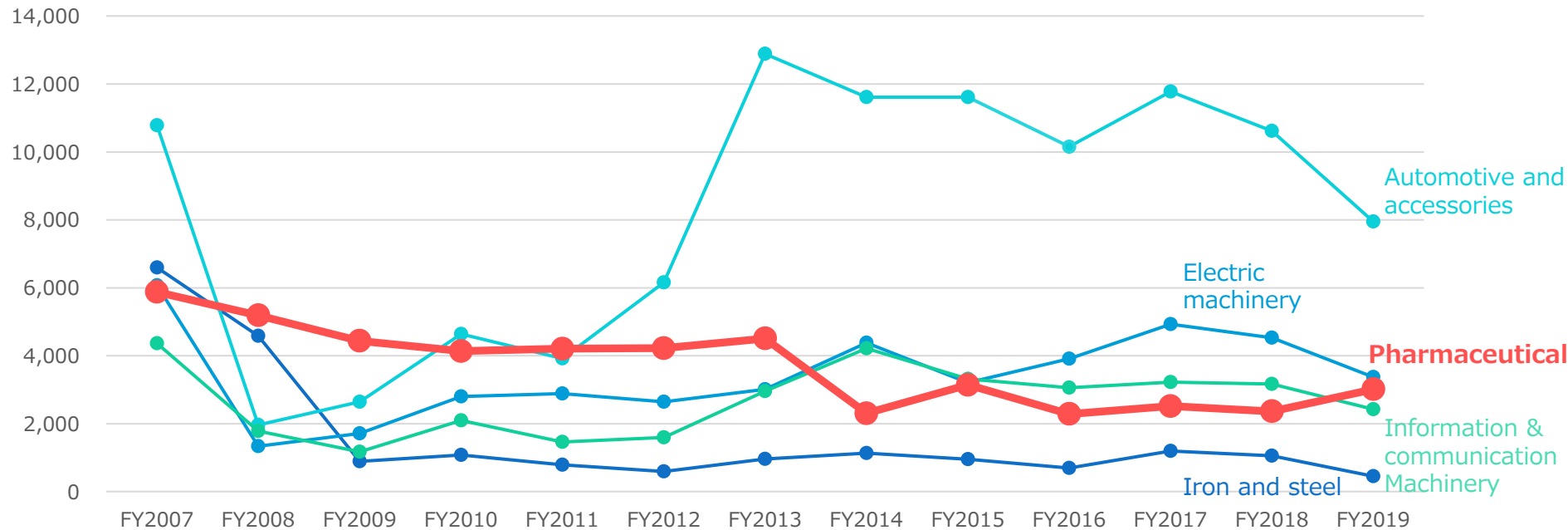
(Sales chart is shaped like a cliff)

Domestic Tax Payments of Japan's Major Manufacturing Sectors



- The pharmaceutical sector contributes to the Japanese economy with its stable tax capacity

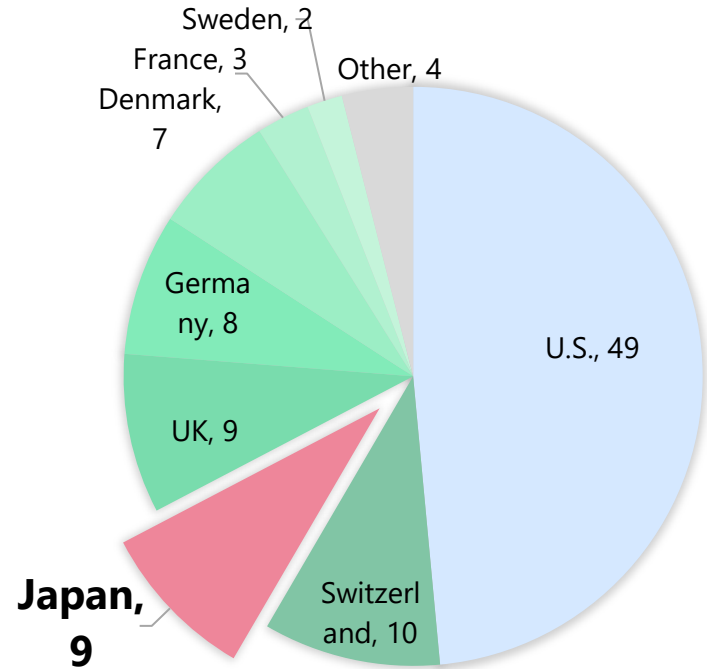
(100 million yen)



Number of Drugs Developed by Major Country (FY2019)



- Only a handful of countries can discover new drugs
- Japan ranks third in the world for new prescription drug discovery
- Japan is the only Asian country that discovers new prescription drugs



Development and spread of scientific technology

- Industry-academic-government cooperation
- Challenge of cutting-edge fields
- Fostering and use of advanced and diversified human resources

Mission as a life-related industry

“Contributions to the improvement of health and welfare of people in the world”

Contributions to economic growth

- Stable and high-level tax-bearing capacity
- Pharmaceutical industry as a high-value added industry
- Investment in R&D

Realization of a society of health and longevity

- Contributions by new drugs
- Efforts to satisfy unmet medical needs
- Efforts to overcome intractable diseases
- Elimination of drug lag

Contributions to the global health community

- Global development of new drugs
- Alliance with Asian countries
- Role of Japan in the creation of new drugs
- 3 major infectious diseases and NTDs*



Contributions to COVID-19

- Stable supply of pharmaceuticals
- Promotion of R&D of therapeutic drugs and vaccines, etc.

2. What's SHIONOGI

Shionogi Known for "MUSIC FAIR," "SEDES," "Popon S," etc.



- Broadcast for more than 50 years since August 31, 1964, under the sole sponsorship of Shionogi
- The longest running music program on commercial TV in Japan



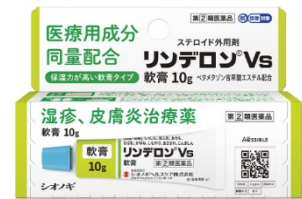
Designated class 2 OTC drug



Designated class 2 OTC drug



Designated quasi-drug



Designated class 2 OTC drug



Designated class 2 OTC drug



Class 3 OTC drug



Class 2 OTC drug

What's SHIONOGI - philosophy -



Shionogi's purpose

Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.

For this purpose, Shionogi will need to:

Pursue the search for even better medicines.

Produce even better medicines.

Promote awareness of these better medicines to more people so that more people will be able to use these medicines.

Research, produce and promote in an even more economical manner.

For this purpose, Shionogi people will need to:

Strive ceaselessly day after day to improve their skills.

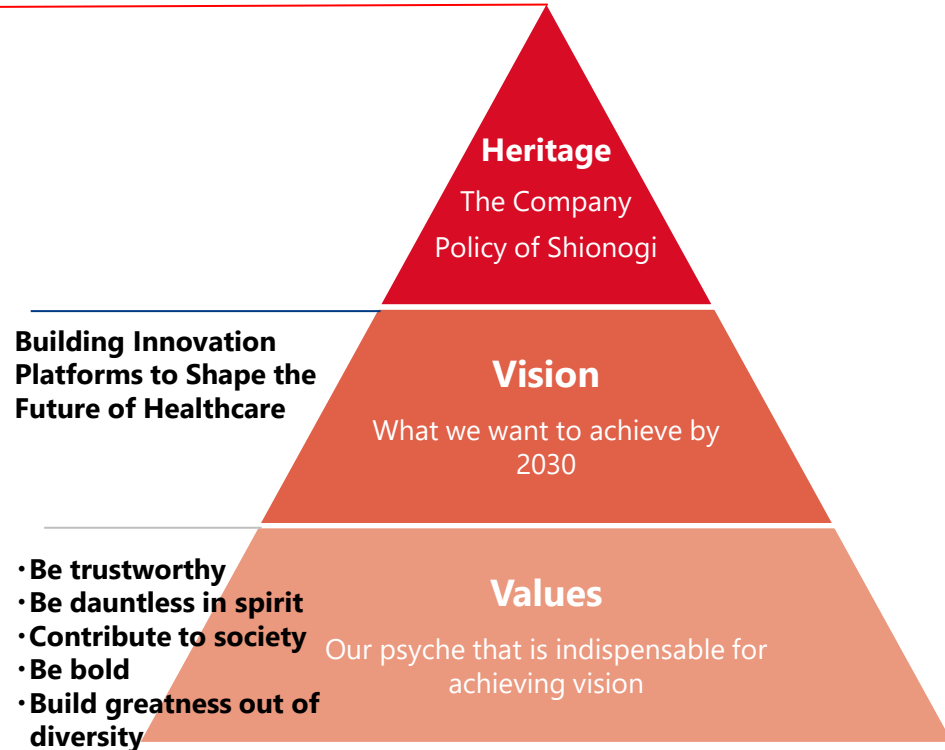
Strive ceaselessly day after day to improve as human beings.

As a result, Shionogi people will:

Find even greater satisfaction in their daily work and in their daily lives.

Find even greater improvement in the quality of their lives.

Find even greater prosperity in their lives. (Established on January, 1957)



SHIONOGI – company profile –

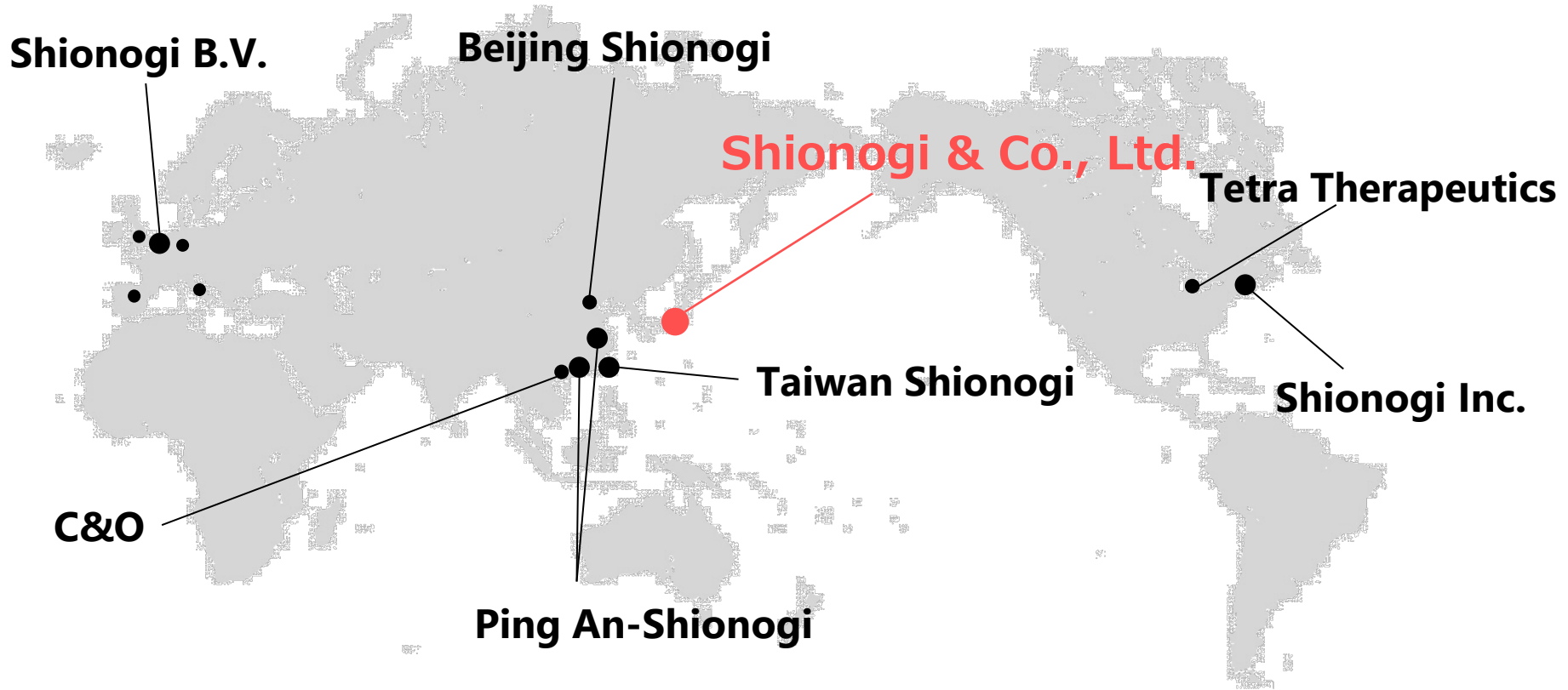


Shionogi & Co., Ltd., based in Osaka, is a prescription drug-based pharmaceutical company founded more than 140 years ago, aiming to contribute to people's health as a "HaaS** company" that provides healthcare services

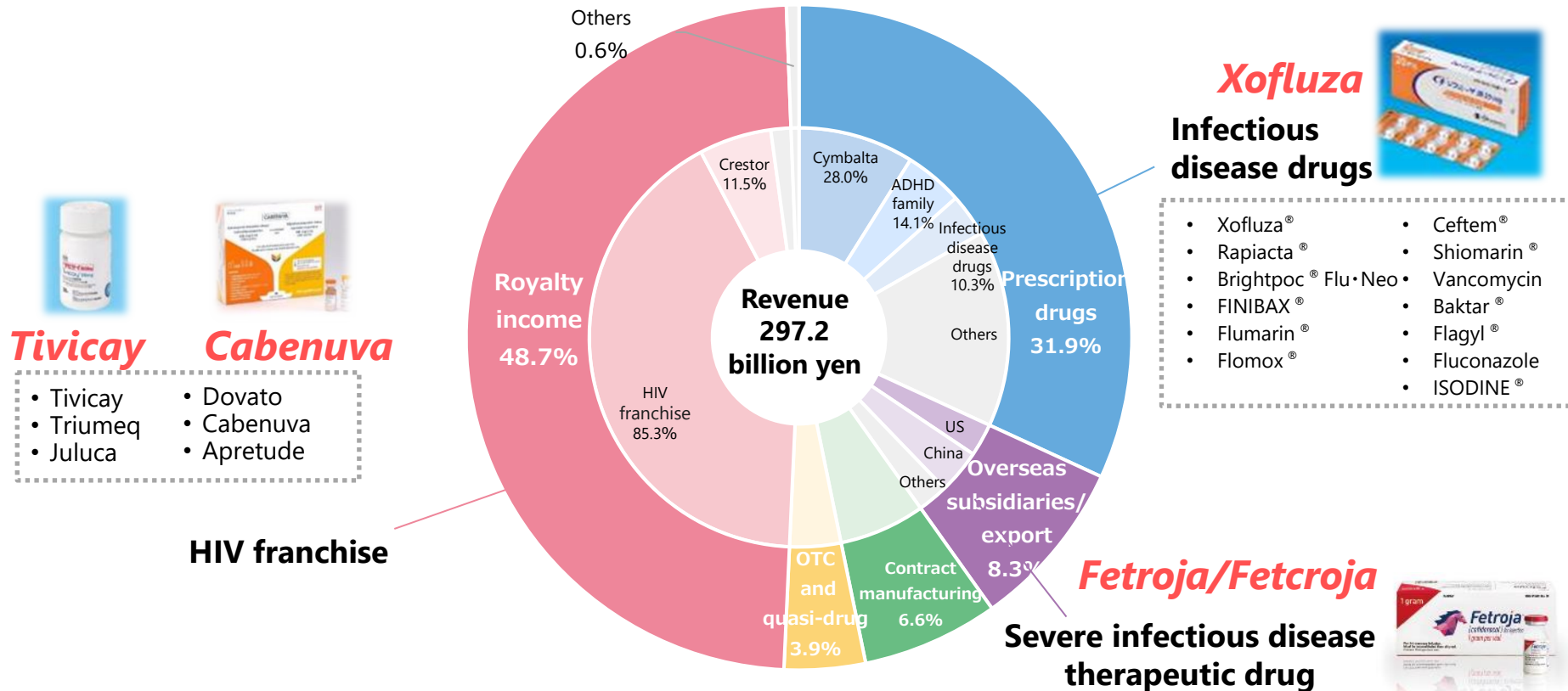
Corporate Name	SHIONOGI & CO., LTD.
Chief Executive	President and CEO: Isao Teshirogi, Ph.D.
Established	March 17, 1878 in business for 144 years
Incorporated	June 5, 1919
Head Office	Doshomachi, Chuo-ku, Osaka, Japan
Number of Employees	5,485 (consolidated)
Category of Business	Marketing and Manufacturing of Drugs
Type of Business	Manufacturing and distribution of pharmaceuticals, diagnostic reagents and medical devices, etc.
Consolidated Revenue	¥ 297.2 billion** (Prescription drugs 96% and OTC and quasi-drugs 4%)
Operating profit	¥117.4 billion** (Operating profit margin: 39.5%)



What's SHIONOGI -global expansion -



What's SHIONOGI - revenue composition (FY2020)-



What's SHIONOGI -Shionogi's strengths-



R&D

More than 10 new, in-house discovered drugs have been launched since 2000 when we embarked on transformations



Diverse partnering

Discover innovative new drugs in-house and provide to patients across the world through partnering that maximizes the value of compounds



Know-how of infectious diseases

Pursue total care of infectious diseases by harnessing our know-how accumulated over more than 60 years through R&D of infectious diseases



Human resources

Promote the "development and building of strong individuals and organizations capable of surviving global competition"



Shionogi's History in Infectious Disease Area

-In-house discovered Infectious Diseases Drugs-



1878

Shiono Gisaburo Shoten founded as a drug wholesaler at the present site of the head office, Doshomachi, Osaka

1959

The sulfonamide drug **"Sinomin[®]"**

1982

The oxacephem antibiotic **"Shiomarin[®]"**

1988

The oxacephem antibiotic **"Flumarin[®]"**

1997

The cephem antibiotic **"Flomox[®]"**

2005

The carbapenem antibiotic **"Finibax[®]"**

2014

The HIV treatment **"Tivicay[®]"** ※Developed by ViiV

2018

The anti-influenza virus drug **"Xofluza[®]"**

2020

A siderophore cephalosporin antibiotic **"Fetroja[®]"** ※Not approved in Japan

2021

The long-acting HIV treatment **"Cabenuva[®]"** ※Not approved in Japan, Developed by ViiV

Shionogi has been engaged in research and development of infectious disease drugs for about 60 years



"Sinomin"
Launch in 1959



"Finibax"
Launch in 2005



"Tivicay"
Launch in 2014



"Xofluza"
Launch in 2018



"Fetroja"
Launch in 2019 (US)

3. Sustainable Growth as as a Leading Company in Infectious Diseases

-Aiming to Protect People Worldwide from the Threat of Infectious Diseases-

Shionogi's Growth History



1st MTBP*
(FY2000 – FY2004)

Focus on pharma business

2nd MTBP
(FY2005 – FY2009)

Expansion of R&D and establishment of global structure



"Crestor"
Launch in 2005

"Finibax"
Launch in 2005

3rd MTBP
(FY2010-FY2013)

Toward global growth



"Tivicay"
Launch in 2014

SGS2020**
(FY2014 – FY2019)

Grow sustainably as a drug discovery-based pharmaceutical company with society



"Xofluza"
Launch in 2018



"Fetroja"
Launch in 2019 (US)

STS2030***
FY2020~

Building Innovation Platforms to Shape the Future of Healthcare

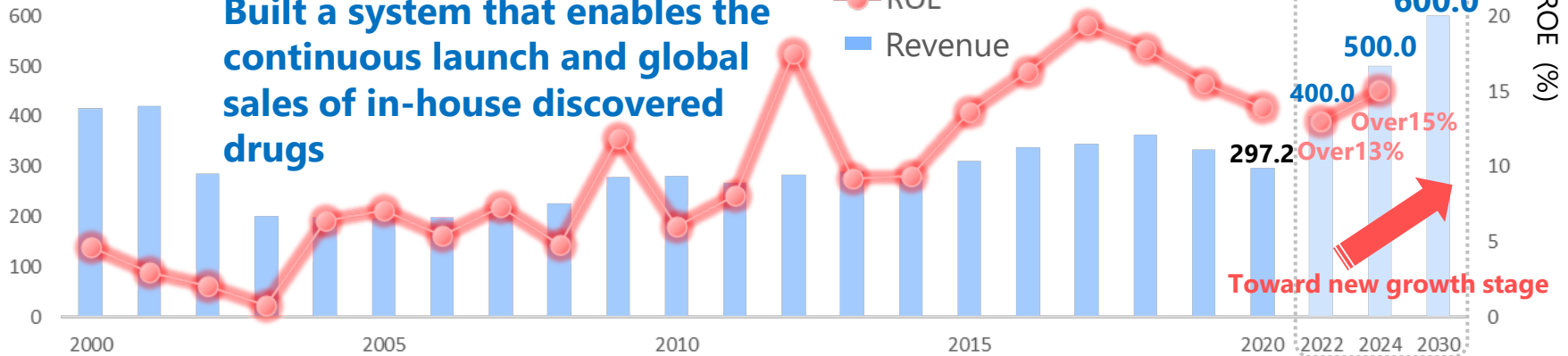


"CABENUVA"
Launch in 2021 (US)

Revenue (B yen)

Built a system that enables the continuous launch and global sales of in-house discovered drugs

—●— ROE
—■— Revenue



Toward new growth stage

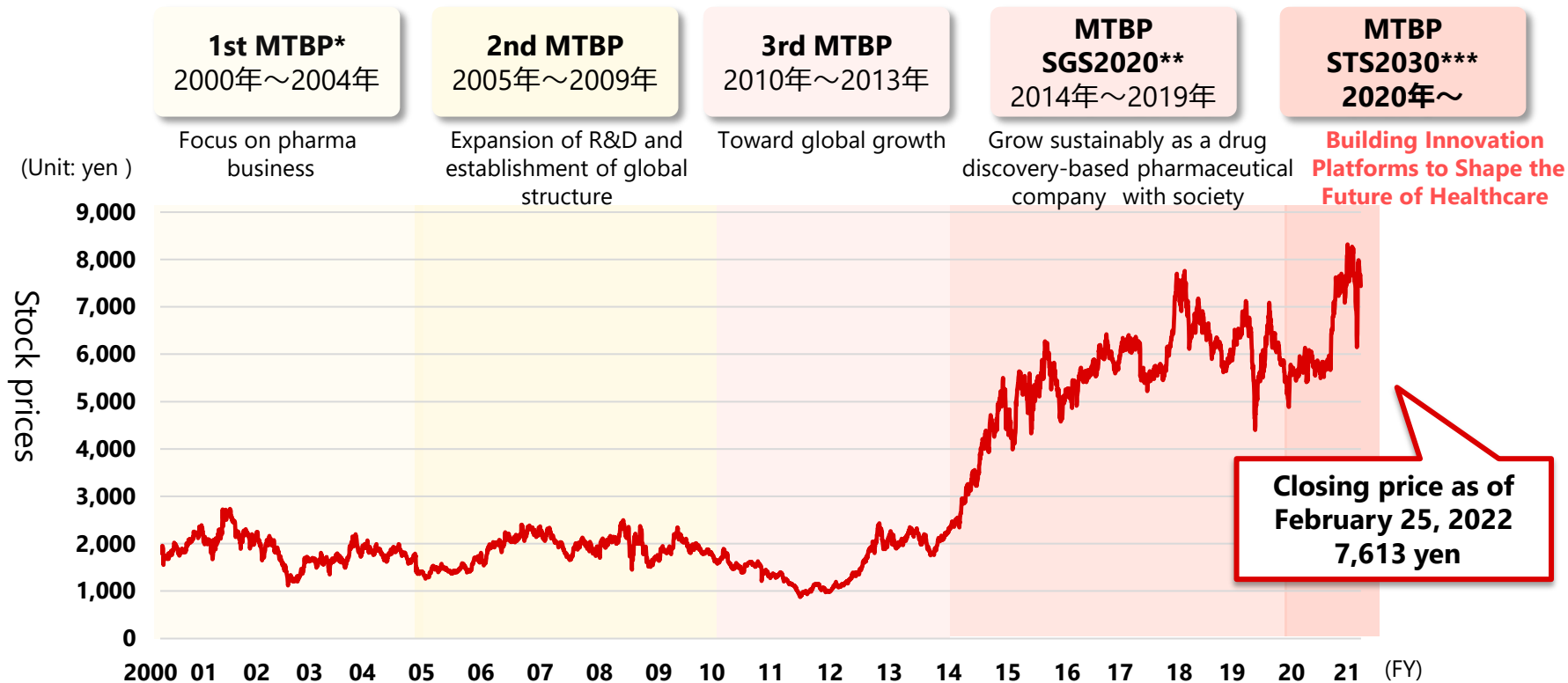
High Operating Profit Margin

Comparison of operating profit ratio of major pharmaceutical companies



**With a strong presence,
to be a company that consistently grows as it contributes to society**

Stock Price Changes



Stock prices are steadily increasing due to the progress of the medium-term business plan

Vision 2030

**Building Innovation Platforms
to Shape the Future of
Healthcare**

Strategy to achieve 2030 Vision

STS2030

- Shionogi Transformation Strategy 2030 -



STS2030

STS Phase 1 ('20-'24)

STS Phase 2 ('25-)

Three strategies for STS Phase1

New value creation

i. R&D strategy



Development of innovative pipeline

ii. Top-Line
iii. Strategy



Business growth through creation of diverse businesses

Infrastructure building

iii. Management Foundation Strategy

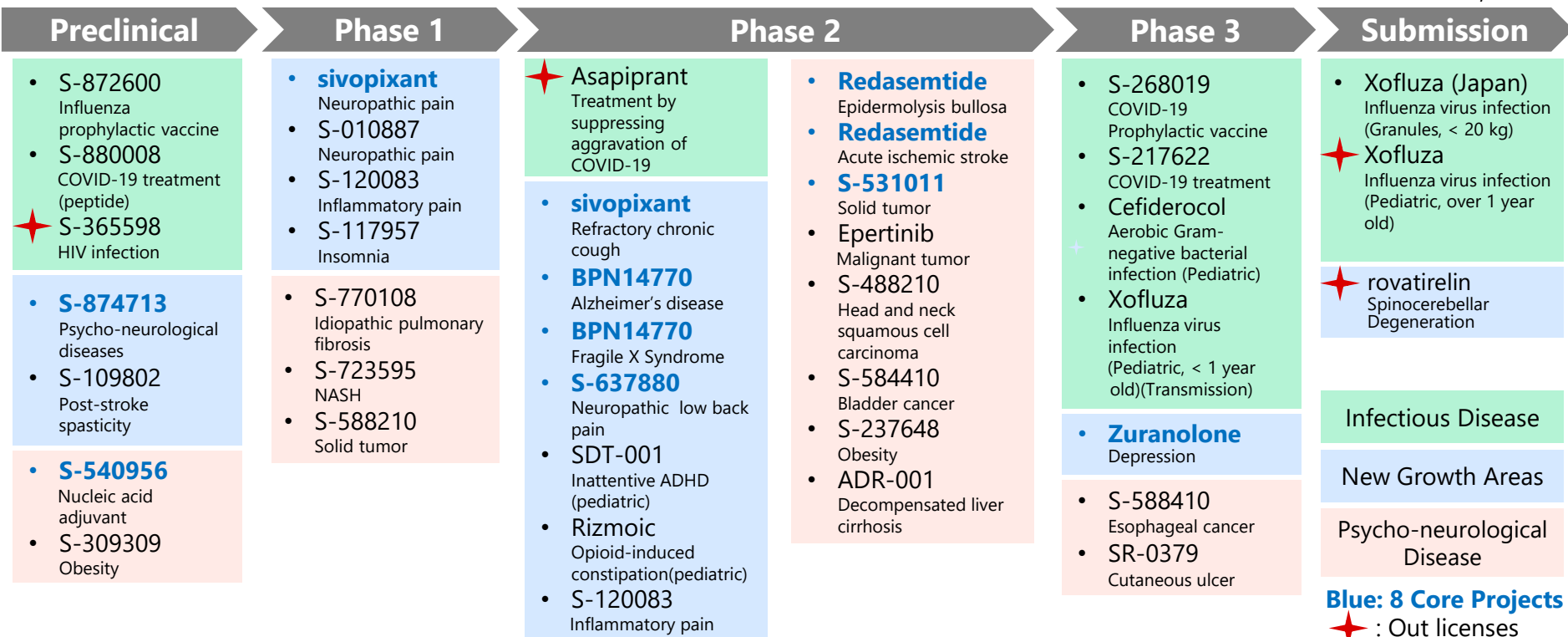


Building framework for new value creation

Pipeline Forming the Basis of Growth



as of Jan. 31, 2022



Blue: 8 Core Projects

★ : Out licenses

Aim for sustainable growth by continuously providing innovative new drugs

KPI in STS2030

	KPI	FY2020	FY2022	FY2024	FY2030
Growth	Revenue	297.2 B yen	400.0 B yen	500.0 B yen	600.0 B yen
	Core operating profit*	94.0 B yen	120.0 B yen	150.0 B yen	200.0 B yen
	Core operating profit margin	31.6%	Over 30%	Over 30%	-
	Overseas sales ratio (excl. RYT)	16.2%	Over 25%	Over 50%	-
	Original pipeline ratio	71%	Over 60%	Over 60%	-
Shareholder return	EPS	365 yen	Over 370 yen	Over 480 yen	-
	DOE	4.1%	4%以上	Over 4%	-
	ROE	13.9%	Over 13%	Over 15%	-

Social Issues to be Tackled by Shionogi



Contribution to SDGs



• SDGs that Shionogi can help to achieve

- **Goal 3: Good health and well-being**
- Goal 8: Decent work and economic growth
- Goal 9: Industry, innovation, infrastructure
- Goal 12: Responsible consumption, production
- Goal 17: **Partnerships for the goals**



Priority tasks

- **Protect people worldwide from the threat of infectious diseases**
 - **Develop infectious-disease-related products and communicate accurately about them**
 - Three major infectious diseases (HIV, TB, malaria)
 - AMR/viral infectious diseases (influenza, corona, etc.)
- **Improve social productivity and extend healthy lifespans**
 - **Contribute to increasing productivity**
(address chronic pain, depression, etc.)
 - **Meet the needs of the super-aging society**
(address dementia, cancer, etc.)
- **Contribute to sustainable social security**
 - **Provide medical care optimized for the individual**
 - **Deliver healthcare solutions at prices that are commensurate with their value**

As a Leading Company in Infectious Diseases



Shionogi's strengths

- **Know-how of infectious diseases**
- **R&D**
 - Small-molecule drug discovery
- **Diverse partnering**
- **Human resources**



Key material issue

Protect people worldwide from the threat of infectious diseases

Infectious disease initiatives

1. **Viral infectious disease initiatives**
 - Initiatives for early containment of COVID-19*
 - Influenza initiatives
2. **Development of drugs for the three major infectious diseases**
 - HIV franchise advancement
3. **Contribution to tackling serious infectious diseases incl. AMR bacteria**
 - Launch of Cefiderocol and promotion of proper use
4. **Establishment of new business model for infectious diseases**
 - Establishment of a sustainable business model

Achieve medium to long-term growth while solving social issues mainly in our core area of infectious diseases

1. Viral infectious disease initiatives (COVID-19)

Actions for Early Containment of COVID-19



Epidemic forecasting



- Sewage epidemiology surveillance service for early detection of COVID-19 incursion and outbreak trends

Prevention



- Development of a recombinant vaccine for COVID-19 (**S-268019**)

Diagnosis



- Antigen-test kit
- Th2 chemokine TARC* kit for assisting in predicting exacerbations
- Novel rapid diagnostic method

Treatment



- Discovery and development of novel antiviral drug (**S-217622**)
- Discovery of developmental candidate peptide

Exacerbation suppression



- Licensing out asapirant, an exacerbation controlling candidate

Providing solutions for the overwhelmed medical system

1. Viral infectious disease initiatives (COVID-19)

COVID-19 Therapeutic Drug: S-217622



The environment surrounding the COVID-19 oral therapeutic drug and the significance of a domestic therapeutic drug

- **Only two drugs are available in the world**
 - Molnupiravir (Merck) = US: EUA*; Japan: specially approved
 - PAXLOVID (Pfizer) = US: EUA*; Japan: specially approved
- **Planned global supply**
 - Merck : 20 million doses by end of 2022
 - Pfizer : 120 million doses by end of 2022

Even mega pharma that have provided billions of doses of vaccines in a short span of time can only provide a limited amount of oral therapeutic drug

- **Significance of a domestic therapeutic drug**
 - Shionogi plans to produce 1 million doses of S-217622 in FY2021 and 10 million doses in FY2022
 - **Ensure stable production and supply prioritizing Japan**

1. Viral infectious disease initiatives (COVID-19)

COVID-19 Therapeutic Drug: S-217622



Profile

- 3CL protease inhibitor
- Once-daily oral administration for five days
- Confirmed antiviral activity against the omicron variant strain as strong as against existing variant strains (nonclinical trial)
- Assumed patients
 - **Irrespective of high risk factors or vaccination**
 - Patients with mild or moderate symptoms and asymptomatic patients

Development status

- **Applied for approval of production and sales (February 25, 2022)**
- Top-line results of the Phase 2b Part
 - A significant antiviral benefit against placebo
 - A significant improvement compared to placebo in respiratory symptoms characteristic of the omicron variant
 - No adverse event of concern has been recognized

Supply

- Production plan
 - 1 million doses in Japan by end of March 2022
 - More than 10 million doses per year in FY2022



Future time schedule

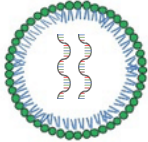
- Japan
 - Mild/moderate: ongoing Phase 3 part
 - Asymptomatic/only mild symptoms: ongoing Phase 2b/3 part
- Global
 - Global Phase 3 trial scheduled to be initiated

1. Viral infectious disease initiatives (COVID-19)

Types of Vaccine Antigen Production Technology

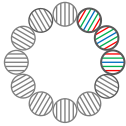


mRNA vaccine
(*COMIRNATY)
(*Spikevax)



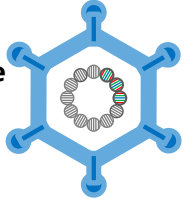
Stabilization by conversion from RNA to DNA

DNA vaccine
(AG0302-COVID19)

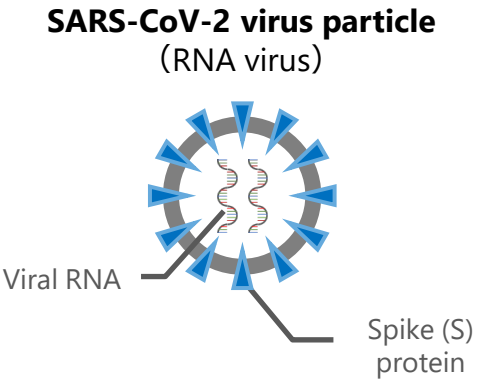


Protection of DNA by shells such as adenovirus


Virus vector vaccine
(*Vaxzevria)



New generation technology

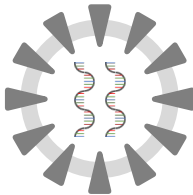


Recombinant protein vaccine
(S-268019)



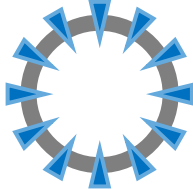
Inactivation of virus by heat/chemical treatment

Inactivated vaccine
(KD-414)



Empty virus particles without genome

****VLP vaccine**
(*COVIFENZ)



Traditional technology

1. Viral infectious disease initiatives (COVID-19)

COVID-19 Vaccine: S-268019



Profile

- Recombinant protein vaccine
- **Aim to be approved both priming and booster indication**

Supply

- The development of a supply system for **more than 30 million doses** is planned in cooperation with UNIGEN (antigen production) and API (formulated product manufacturing)

Future time schedule

- Intend to initiate prior consultations on the results of ongoing clinical trials
- Consult with the authorities for domestic application

Ongoing Clinical trials

- Pivotal 5 clinical trials are ongoing **(on the following page)**
 - Phase 2/3 trial
 - Active control, neutralizing antibody titer trial
 - **Placebo control, onset prevention trial**
 - Phase 2/3 booster trial
 - Phase 3 booster trial

Significance of being the only domestic vaccine undergoing a comparative study in Asia to prevent the onset of symptoms

- **Realization of a domestic vaccine that can be provided globally**
 - Japan's contribution to global health and future growth of the industry
- **Realization of "100 DAYS MISSION"**
 - Prepare for any pandemic, beyond COVID-19

1. Viral infectious disease initiatives (COVID-19)

COVID-19 Vaccine: S-268019



Ongoing Clinical Trials

- **Phase 2/3 trial*1:** 3,100 subjects
 - Completed observation through Day 57 with no major safety concerns
 - There are no major safety concerns
 - Topline results will be presented at Annual Meeting of Japanese Association for Infectious Diseases in April 2022
- **Active control, neutralizing antibody titer trial*2**
: 1,000 subjects
 - Superiority trial to compare to VAXZEVRIA intramuscular injection
 - Completed the 1st inoculation of all subjects
- **Placebo control, onset prevention trial*3**
: 54,915 subjects
 - Initiated in Vietnam from December 2021
- **Phase 2/3 booster trial*4:** 204 subjects
 - Non-inferiority verification with COMIRNATY intramuscular injection by booster immunization after 2 doses of COMIRNATY
 - Top-line results: scheduled to be disclosed in early March
- **Phase 3 booster trial*5:** 150 subjects
 - Evaluate the safety of booster immunization after two SPIKEVAX intramuscular injections

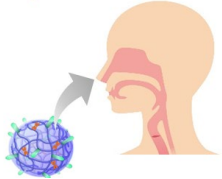
*1 [jRCT2031210383](https://www.clinicaltrials.gov/ct2/show/study/NCT04374604), *2 [jRCT2051210151](https://www.clinicaltrials.gov/ct2/show/study/NCT04374604), *3 [NCT05212948](https://www.clinicaltrials.gov/ct2/show/study/NCT04374604), *4 [jRCT2031210470](https://www.clinicaltrials.gov/ct2/show/study/NCT04374604), *5 [jRCT2031210613](https://www.clinicaltrials.gov/ct2/show/study/NCT04374604)

1. Viral infectious disease initiatives (COVID-19) Direction of Future Vaccine Actions



Development of nasal vaccine

HanaVax



Cationized nanogel delivery system

A drug discovery venture company originating at the University of Tokyo

SHIONOGI

UMN Addressing Unmet Medical Needs
株式会社UMNファーマ



千葉大学
CHIBA UNIVERSITY

- Simple administration with no pain caused by conventional needles
 - Able to effectively induce immunity in respiratory mucosa, which is the area that becomes infected, as well as the entire body
 - Vaccines using BEVS* are widely used, with established efficacy and safety
 - Speedy, low cost, and suited to mass production
 - Specializes in immunization studies
 - Will establish a joint search department for human mucosal vaccines, scheduled to open in April 2022
- **Plan to develop a nasal vaccine against COVID-19, influenza and pneumococcal in cooperation with an outside partner**
 - **Aim to initiate clinical trials in FY2022**

1. Viral Infectious disease initiatives (Influenza) Influenza Actions

Development of Xofluza[®]

Innovative therapeutic drug for influenza discovered in-house

- High antiviral effect
- Single-dose oral drug for both adults and children
- Early approval, emergency listing
 - ⇒ Approved after approx. 4 months of examination

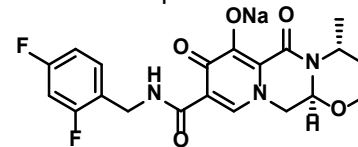


Promptly provide drugs needed by all of society
based on know-how of infectious diseases

Drug discovery on Shionogi's drug discovery platform

Tivicay

- HIV integrase inhibitor
- Potent activity and high barrier to development of resistance



Antiviral drug research x
original compound design

Xofluza[®]

2. Development of drugs for the three major infectious diseases

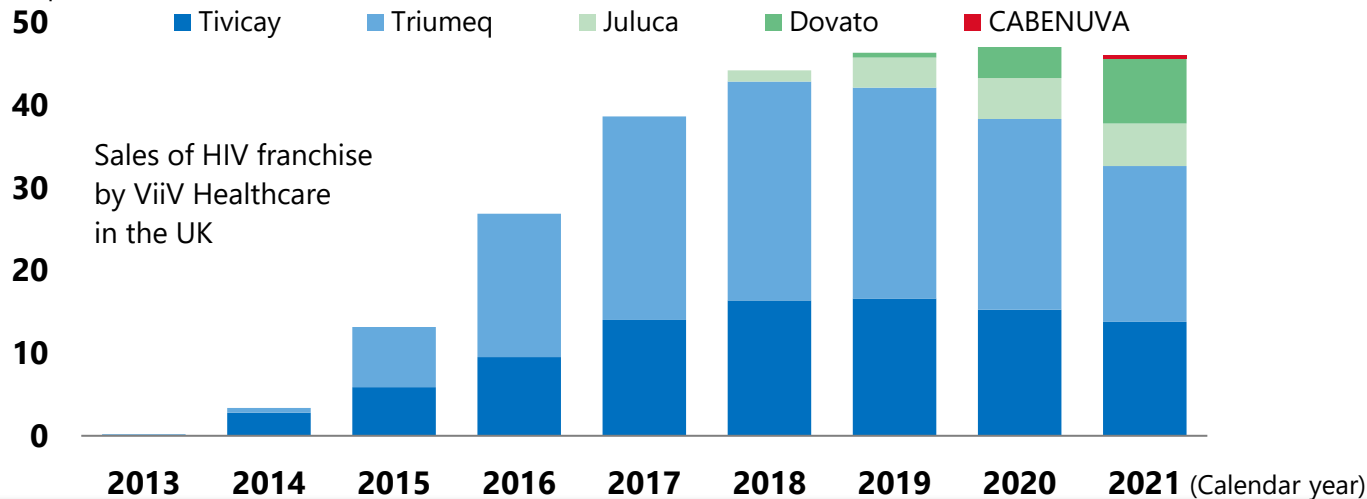
Progress of HIV Franchise by ViiV Healthcare



Growth of sales of HIV franchise out-licensed to ViiV*

- Progress of a two-drug regimen with Tivicay as the key drug
- Increase in RYT and dividends due to advancement of the HIV franchise
 - RYT income from ViiV: 123.4 billion yen; dividends: 23.4 billion yen (FY2020)

(100 million pounds)



2. Development of drugs for the three major infectious diseases

Progress of HIV Franchise by ViiV Healthcare



Further progress with long-acting formulations

- HIV market shifts to long-acting formulations for both treatment and PrEP
 - The treatment and PrEP market for long-acting formulations will grow to £ 4-5 billion each in 2030*

CABENUVA (CAB/RPV**)

The first and only long-acting injectable formulation

- **A Treatment administered once every two months**
 - Reduce the burden of continuing treatment



Apretude (cabotegravir)

Long-acting formulation for PrEP

- **A prevention administered once every two months**
 - Freedom from daily oral administration
- **Paradigm shift in the PrEP market**
 - Higher preventive effect than existing drugs

S-365598

Third-generation HIV integrase inhibitors

- **Administration once every three months or more**
 - Further improvement of convenience
- **Intend to initiate Phase 1 trial by 2023**

Achieve further growth of the HIV franchise with long-acting formulations

3. Contribution to tackling serious infectious diseases incl. AMR bacteria Launch of Cefiderocol and Promotion of Proper Use



Antimicrobial Resistance (AMR)

AMR is difficult to detect and spreads relatively slowly, a serious problem, being referred to as "a slow tsunami that threatens to undo a century of medical progress"

- Deaths due to AMR (annual) ⇒ **0.7 million people**
- Deaths attributable to AMR per year by 2050 ⇒ **Over 10 million people***
- Estimated economic impact ⇒ **\$100 trillion**

AMR measures are "issue to be tackled on a global scale"



In parallel with the launch of a multidrug-resistant gram-negative bacterial infection therapeutic drug Fetroja, continue to promote the proper use to prevent the outbreak of new resistant bacteria and viruses**

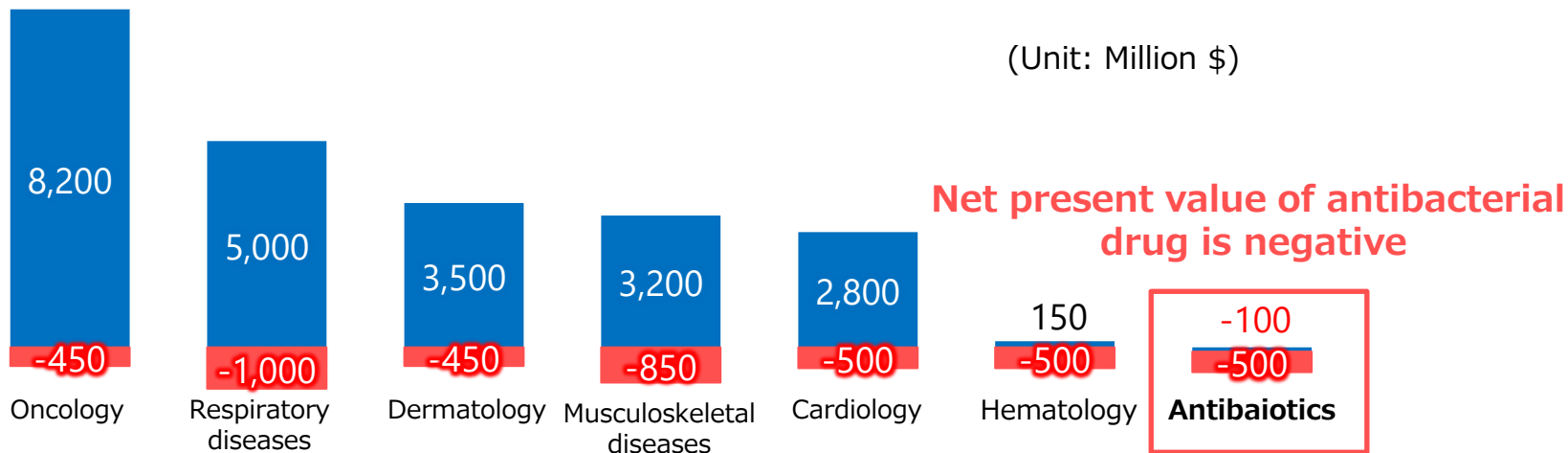
* Estimate when AMR measures are not taken: The Review on Antimicrobial Resistance, 2016 (O'Neill report)
** effective against all three types of carbapenem-resistant pathogens (Acinetobacter baumannii, and Enterobacteriaceae) that the World Health Organization considers as requiring priority action

4. Establishment of new business model for infectious diseases

Difficulty of Infectious Disease Business



Profitability by medical property



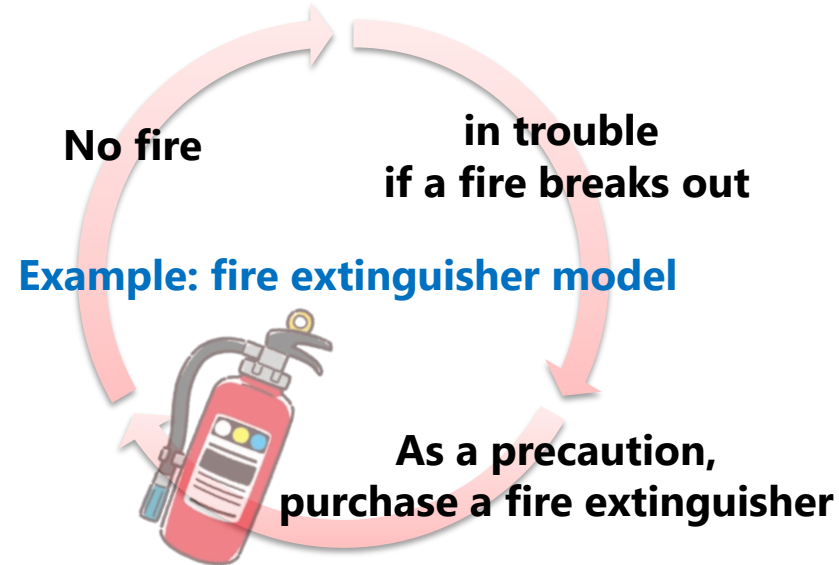
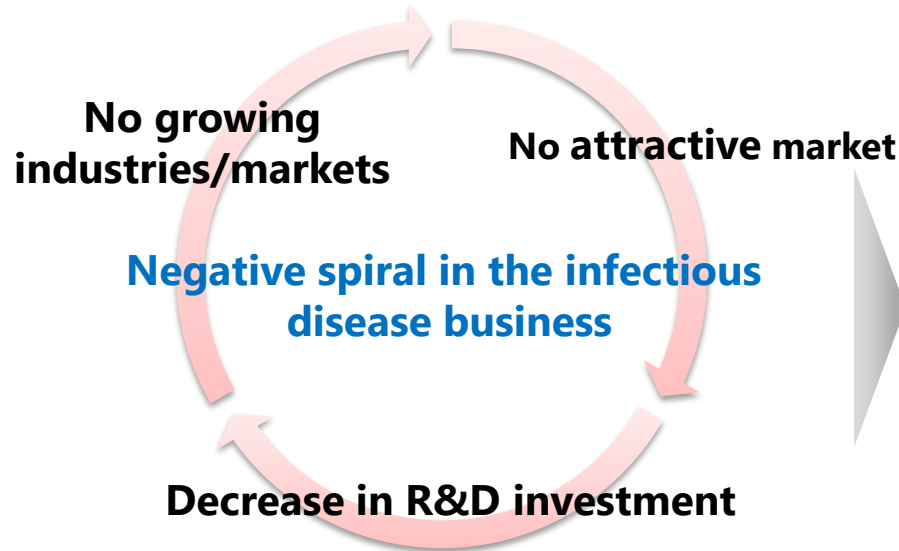
Many companies have withdrawn from antimicrobial R&D due to low profit predictability
Venture companies developing infectious disease drugs also have gone bankrupt

4. Establishment of new business model for infectious diseases

Establishment of a Sustainable Business Model



To build a sustainable business model



Build a model that will be supported by society in normal times* and will make the maximum contribution in an emergency

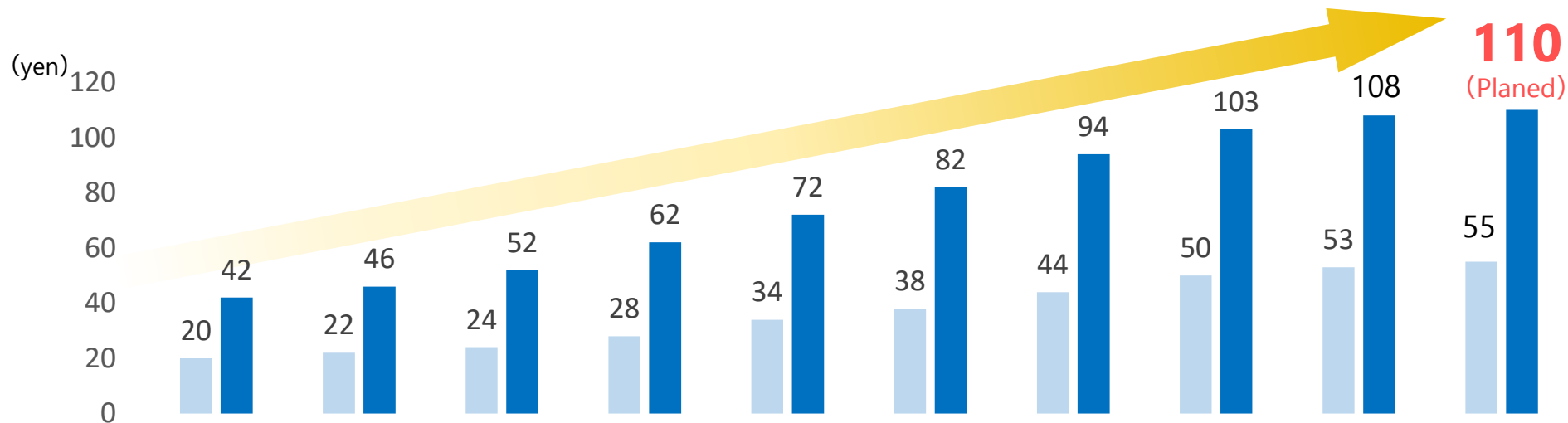
⇒ Need for society as a whole to continue working on infectious disease control

4. Shareholder Return

Shareholder Return Strategy



- Shareholder return policy through which shareholders can feel our growth
 - Plan to increase dividend again for the tenth consecutive year in FY2021



FY		12	13	14	15	16	17	18	19	20	21
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	

Thank You for Your Attention



あしたの感染症と、
たたかっている。

感染症がこの世からなくなることはない。
パンデミックも、きっとまた起こる。
だからこそ、シオノギは逃げずに向き合い続けます。
その時私たちの創るワクチンが、治療薬が、
強く、強く、ひとつでも多くのいのちを守れるように。
薬ができることの、その先へ。



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