

Mid-term Business Plan FY9/2020 – FY9/2024

May 20, 2020

Fuji Pharma Co., Ltd.

TSE1

4554



FujiPharma

Chapter 1

Vision for 2030 and Mid-term Business Plan

- Business Principles and Vision for 2030
- Our Business Domain
- Mid-term Business Plan
- Financial Target

Chapter 2

Growth Scenario and Actions

- Women's Healthcare
- Biosimilar
- Overseas (Asia / North America)
- Contrast Media

Chapter 3

Foundation for Growth

- Toyama Site Mater Plan
- Human Resources
- Sustainability

Chapter 4

Financial Target

- Key Financial Targets
- Key Financial Indices
- Shareholder Return Policy



Chapter

1

Vision for 2030 and Mid-term Business Plan (MTP)

Business Principles and Vision for 2030

We help people lead healthy lives by offering excellent pharmaceuticals

Aspiring to offer significant value in medical care, our key mission is to work together to continuously address challenges and achieve what only we can do in order to gain strong trust and support from medical professionals, and to make greater contributions.

Our corporate growth is proportional to our personal growth

We value bringing happiness to society. The top priority in our corporate management is to continue creating opportunities and situations for further growth by working together to make drugs for medical care.

- Contributing to well-being of women in the world
- Expanding our business to Global Market from Toyama
- Integrating the world happiest company and social contribution

Theme

Fujiらしくをあたらしく "Evolving Fuji"

Target in 9/2029

Goal

Business Plan based
on Vision for 2030

Positioning

Roadmap to achieve
Vision for 2030

Sales

JPY **100** bil+

Growth
Scenario

- No.1 in Women's Healthcare (WH)
- Establish Biosimilar business (BS)
- Strengthen overseas business (OS)
- Evolving into sustainable Contrast Media business (CM)

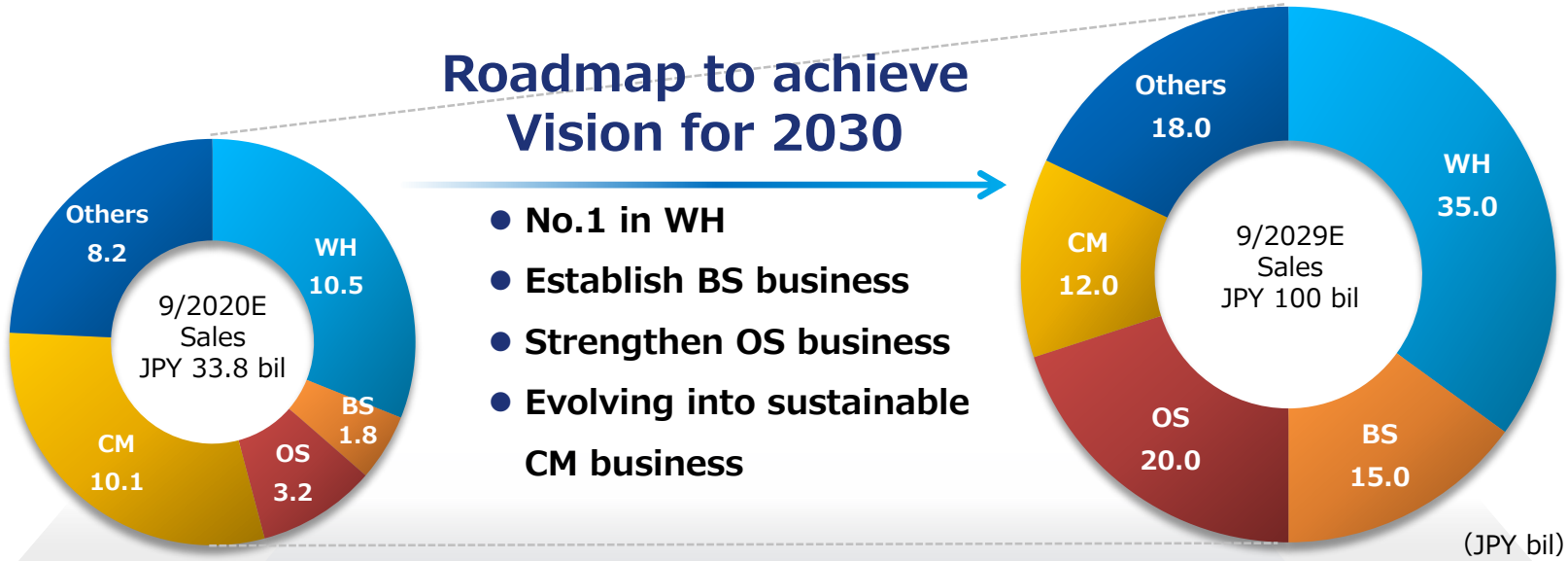
Operating Margin

20%+

To Achieve

Execution through strategic and functional initiatives
Continuous monitoring review semi-annually
Rolled over every year

To Achieve Vision for 2030



MTP 9 Strategies

- ① WH
- ② Injection
- ③ Hormone
- ④ NGT
- ⑤ BS
- ⑥ Asia
- ⑦ N. America
- ⑧ HR
- ⑨ Sustainability

NGT: New Generation Technology

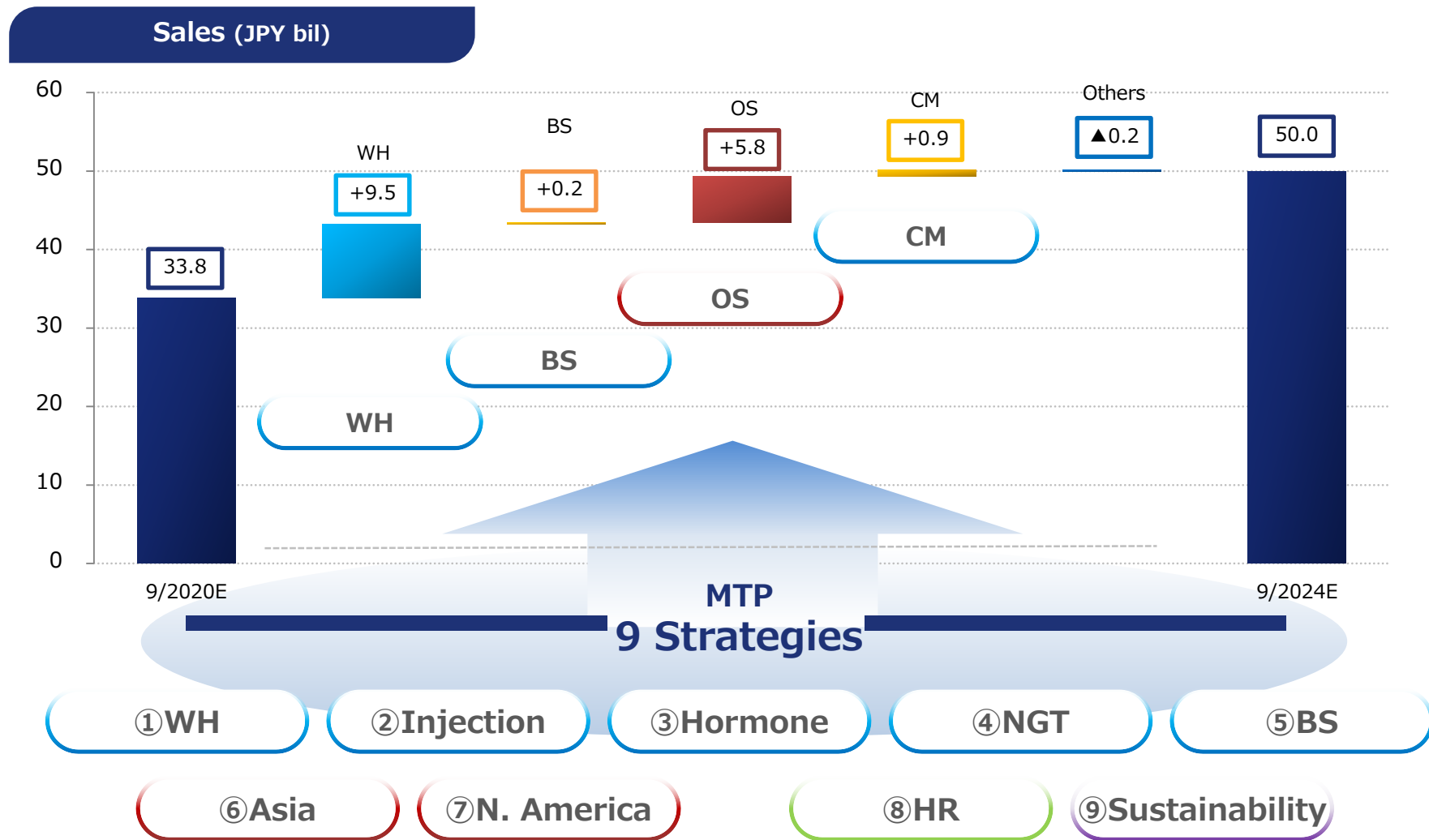


MTP 9 Strategies

Growth Strategy	Strategy	Target in 9/2029
Category X Modality	①WH	<ul style="list-style-type: none"> ✓ No.1 in WH platform ✓ New product launches (mainly hormone) ✓ Contribute to women's well-being not only by drugs ✓ Digitalization
	②Injection	<ul style="list-style-type: none"> ✓ CM new business model is established ✓ Build globally competitive injectable production line
	③Hormone	<ul style="list-style-type: none"> ✓ Large quantity multi-product manufacturing system is built ✓ Men's hormones, anti-cancer, and other products
	④NGT	<ul style="list-style-type: none"> ✓ Difficult-to-make technology is established
	⑤BS	<ul style="list-style-type: none"> ✓ No.1 in Japan BS market ✓ Multiple Alvotech products launched
Area	⑥Asia	<ul style="list-style-type: none"> ✓ Sustainable CMO growth in OLIC ✓ S&M launched in China and ASEAN
	⑦N. America	<ul style="list-style-type: none"> ✓ 505(b)(2) launched by Fuji Pharma USA
HR	⑧HR	<ul style="list-style-type: none"> ✓ Diversified executive officer team ✓ Training programs successfully operated ✓ Language skills improved
Sustainability	⑨Sustainability	<ul style="list-style-type: none"> ✓ "Integrating the world happiest company and social contribution"

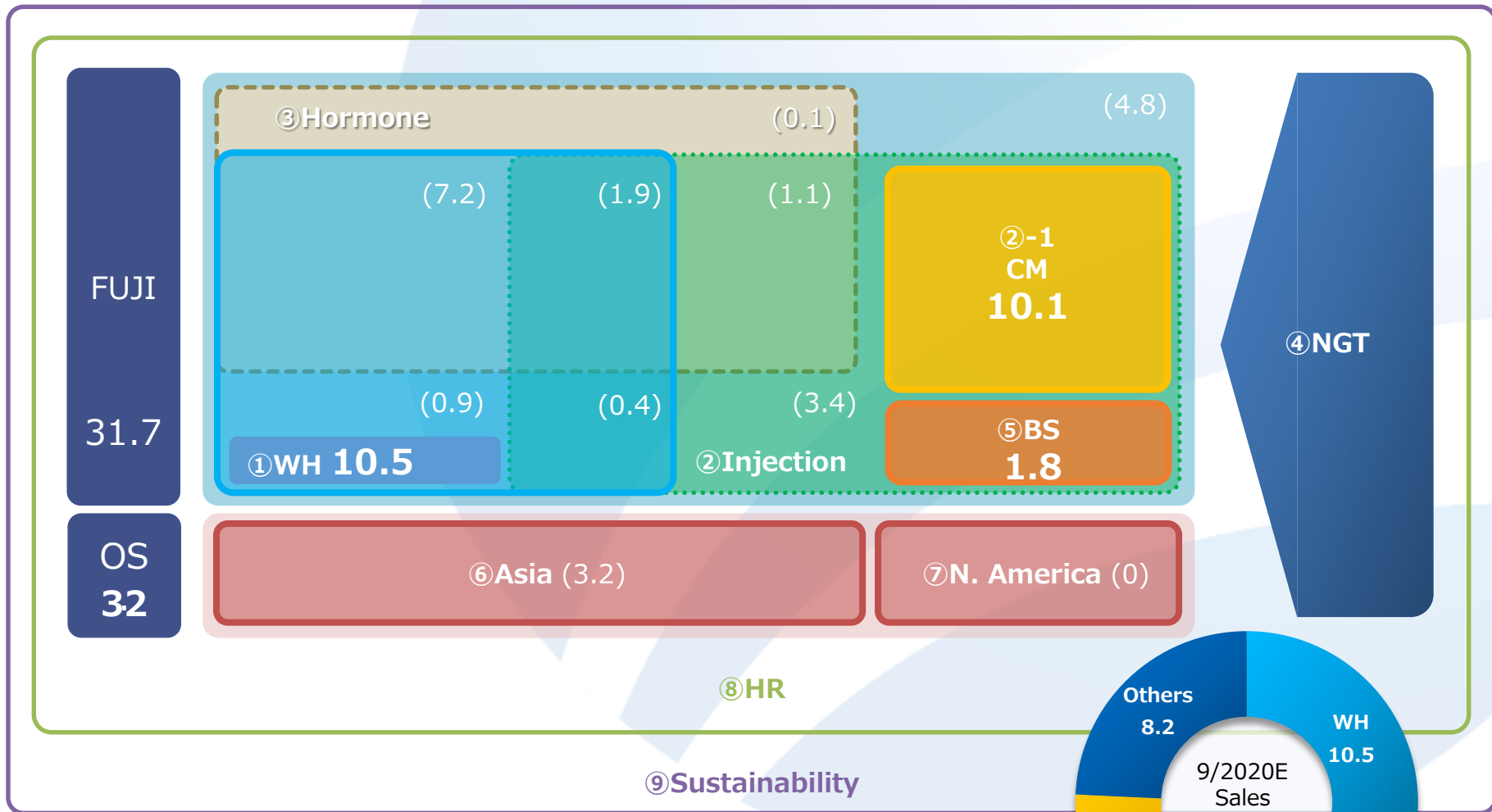
* OLIC: Fuji's subsidiary CMO company (Head office and plant in Thailand)

Financial Target (9/2024)



Our Business Domain

9/2020E Sales / JPY bil





Chapter

2

Growth Scenario and Actions

① Women's Healthcare



① Women's Healthcare

Actions

Hormone products are launched continuously

- Expand product portfolio
- Better production machines and new formulation technologies

Contribute to women's well-being in beyond & around areas

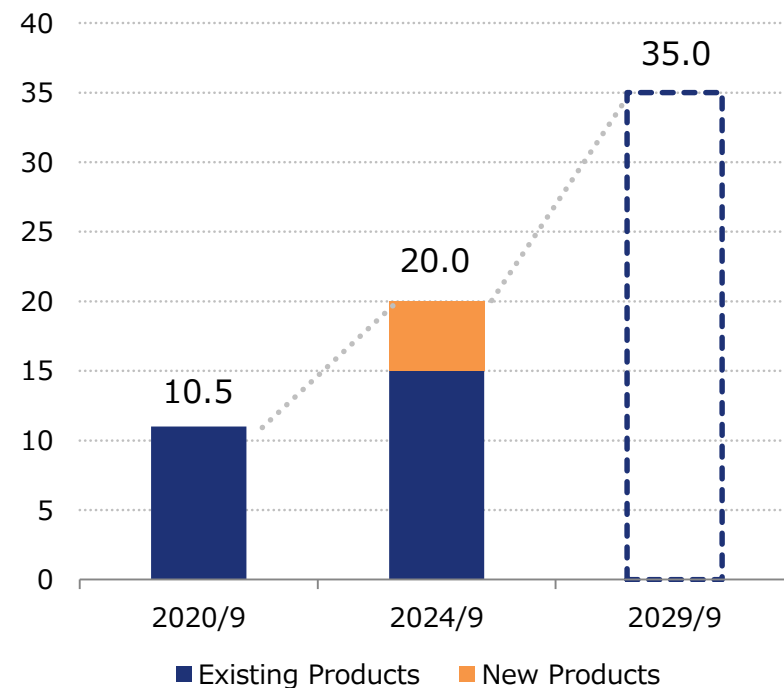
- Enter into beyond/around

Digitalization realizes efficient & effective value creation

- Digitalization
- More effort in detailing to hospitals

(JPY bil)

WH Sales Plan



① Women's Healthcare – Existing Products

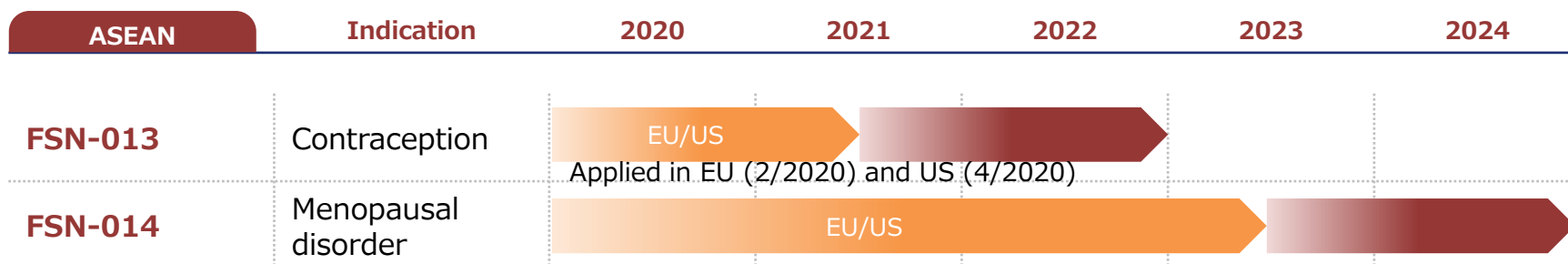
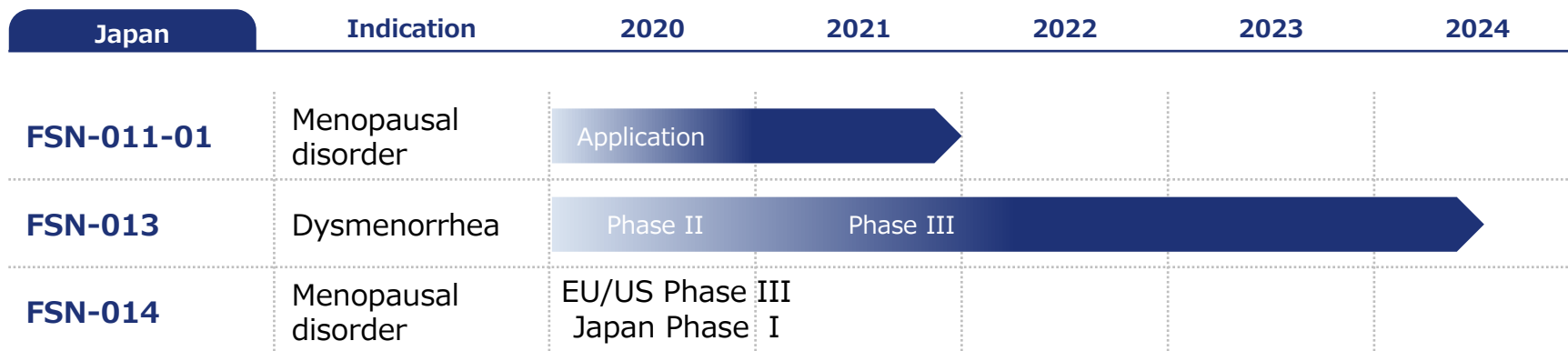
Products	Indication	Status	(JPY bil)	
			2020/9	2024/9
LEVONORGESTREL® (the same)*	Emergency contraception	Market expanded by generic product with 80%+ volume share	0.8	1.5
Favoir® (Ethinylestradiol / Desogestrel)*	Contraception	Domestic oral contraceptive market No.1 volume by manufacturer	0.7	2.7
Labellefile® (Ethinylestradiol / Desogestrel)*			0.7	3.3
UTROGESTAN® (Progesterone)*	Luteal Supplementation in ART	No.2 in clinics	0.8	0.8
DIENOGEST® (the same)	Endometriosis	Market expanded with the record high market share in March	1.1	1.2
l'estrogel® (Estradiol)	Menopausal disorder	CAGR 20%	0.3	0.5
Total			4.6	10.0

* Drug price not listed

ART: Assisted Reproductive Therapy



① Women's Healthcare – New Drug Pipeline



* Time table is shown as Fuji's target

① Women's Healthcare – FSN-011-01 / Progesterone

Overview

- Oral product with Progesterone 100mg
- Utrogestan in combination with an estrogen is used to reduce the symptoms of the menopause
- Approved and launched in 80 countries (e.g. the US and EU)
- Plan to apply and launch with menopausal disorder as an indication

Japan

No progesterone product for Hormone Replacement Therapy

- | | |
|-------------|--|
| 2009 | MHLW solicited requests for the development of unapproved and off-label drugs of high medical need

JSOG and JSMWH submitted request for HRT |
| 2010 | MHLW's committee solicited companies to develop the drug, and Fuji applied |
| 2019 | Phase III test completed |
| 2020 | Plan to apply (September) |

Progesterone: a hormone released by the corpus luteum in the ovary

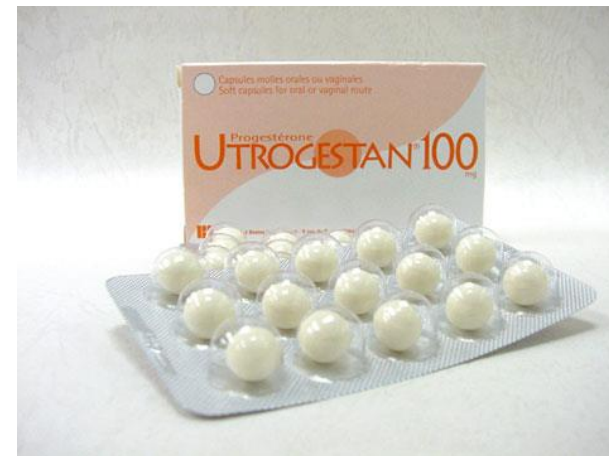


Photo: Utrogestan[®] (marketed outside Japan)

Phase III trial

Trial: Open trial

Target: HRT patients

Term: 52 weeks

Dosage & Administration:

Cyclic: Latter 14 days of 1 cycle (28 days), once a day, 2 capsules orally

Continuous: 28 days of 1 cycle (28 days), once a day, 1 capsule orally

Result: Good outcomes for key evaluation items and tolerability

① Women's Healthcare – FSN-013 / Estetrol/Drospirenone

FSN-013

5th generation OC
New drug for dysmenorrhea

Overview

- Estetrol 15mg + Drospirenone 3mg
- Applied in Europe (EMA) and the US (FDA)

Characteristics

- Lower coagulant impact compared with existing products
- Lower interaction among drugs
- Expect better bleeding control
- Lower lipid impact
- Less likely to gain weight

Japan

Indication: Dysmenorrhea
Stage: Phase II
Launch: 2024 (target)

ASEAN

Indication: Contraception
Stage: Applied in US/EU
Launch: 2022 (target)

Japan (Phase II trial)

Trial: Open trial

Target: Healthy female adults

Term: 3 cycles

Dosage & Administration:

Cyclic: 1 cycle (28 days), once a day, 1 tablet orally for 24 consecutive days followed by placebo for 4 consecutive days

Continuous: 1 cycle, once a day, 1 tablet orally for 28 consecutive days

Result: Good pharmacodynamics outcomes for key evaluation items at the same level as overseas trial, and good tolerability

Overseas (Phase III trial)

Trial: Open trial

Target: Healthy female adults

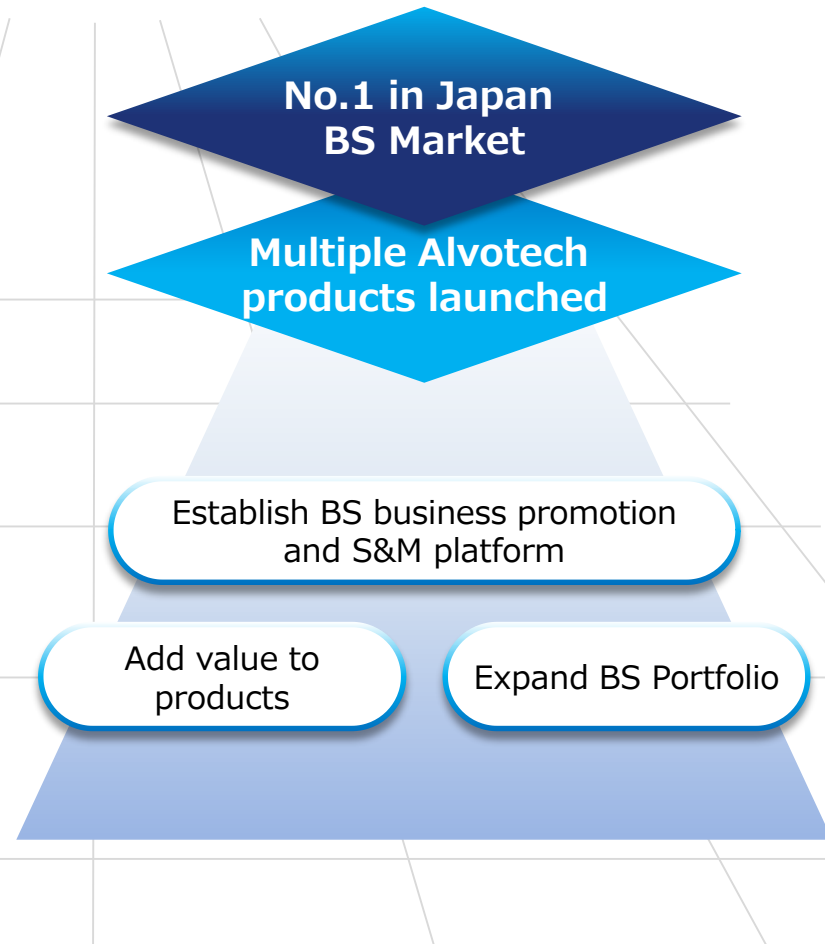
Term : 52 cycles

Dosage & Administration:

1 cycle (28 days), once a day, 1 tablet orally for 24 consecutive days followed by placebo for 4 consecutive days

Result: Good efficacy outcomes for contraception. Good safety outcomes for bleeding control and tolerability.

⑤ Biosimilar



⑤ Biosimilar

Actions

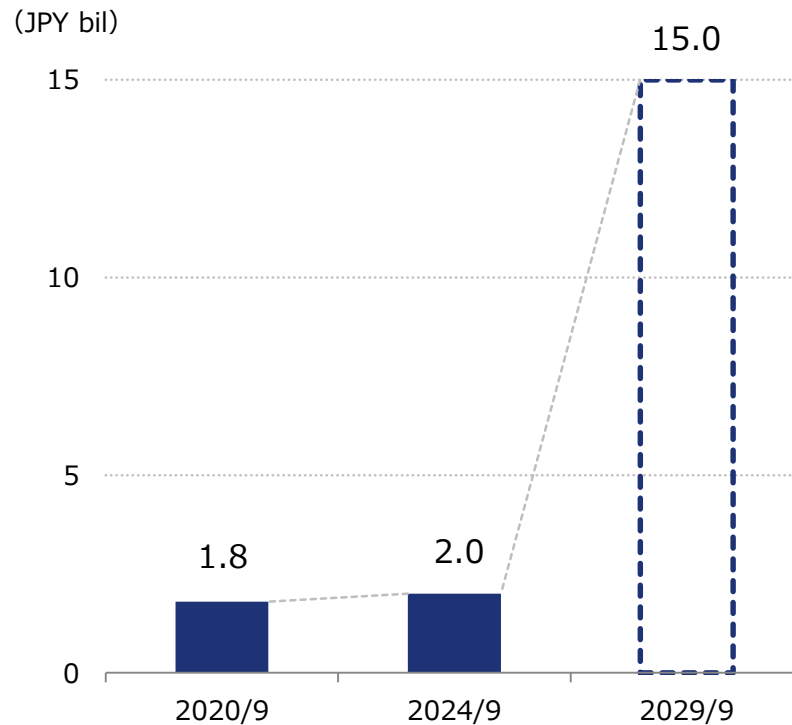
Multiple Alvotech products launched

- Alvotech products to be consistently launched as first in market
- Expand BS portfolio

Establish marketing platform

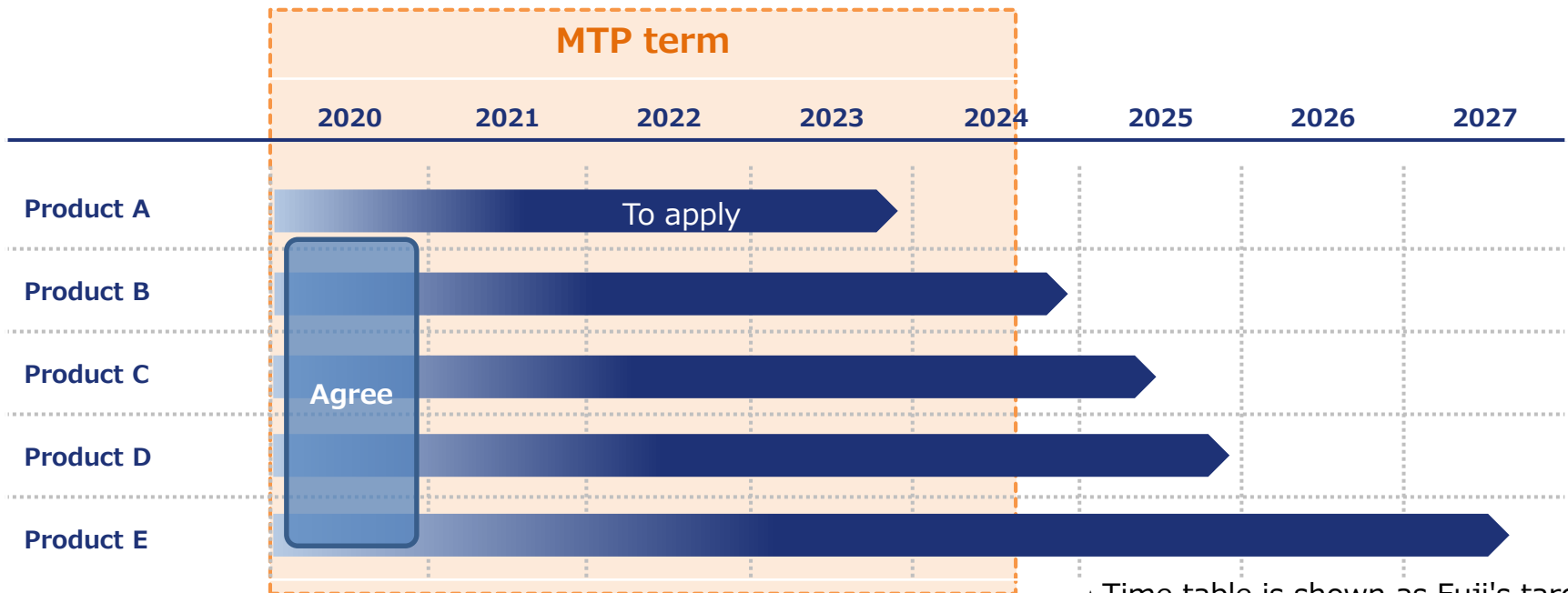
- Establish BS business promotion and S&M platform

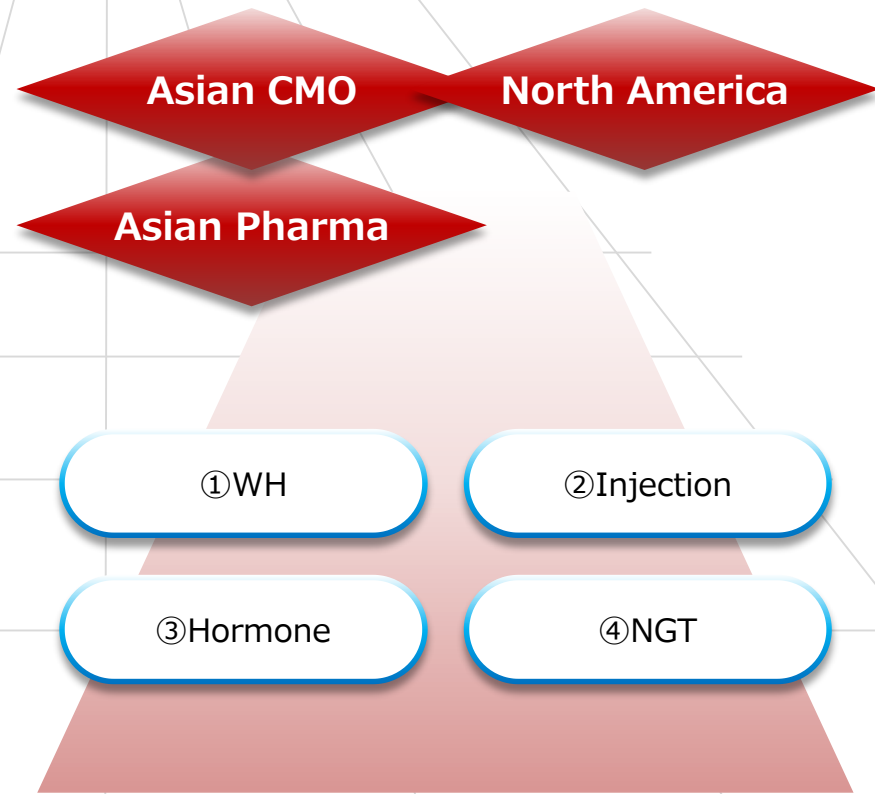
BS Sales Plan



⑤ Biosimilar – Current Status

- November 2018, agreement with Alvotech hf. on an exclusive partnership for the commercialization of biosimilars in Japan
- Discussions has begun on seven investigational drugs (total domestic market size JPY 250 billion) for autoimmune disorder, malicious tumoral diseases, etc.
- Agreed on one product and plan to agree on 4 products shortly (total domestic market size JPY 200 billion for 5 products)





Overseas ⑥Asia / ⑦North America

Actions

Asian CMO
Sustainable CMO growth in OLIC

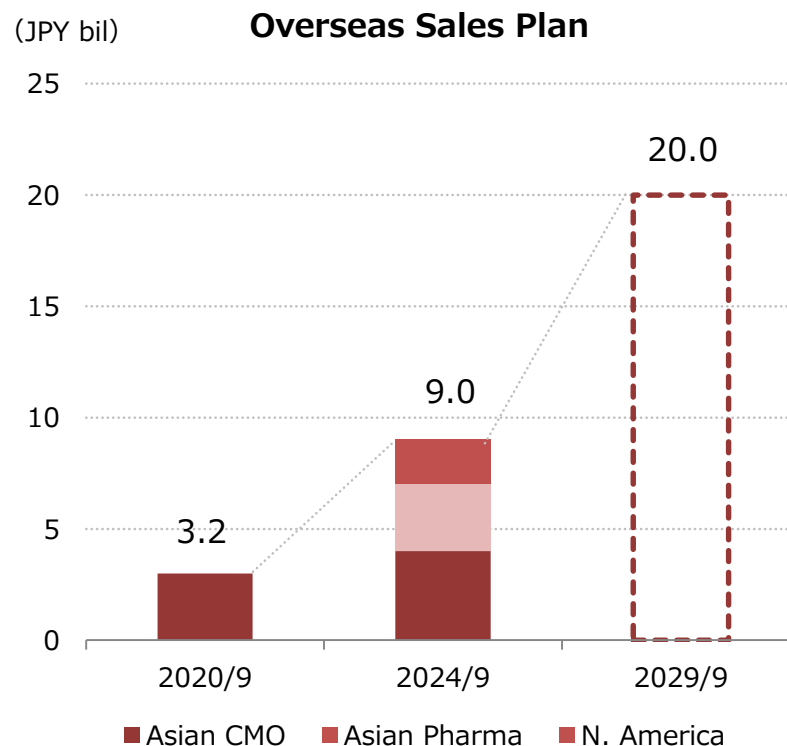
- Expand customer portfolio
- Obtain competitive manufacturing technology
- Higher productivity and cost reduction

Asian Pharma
S&M launched in China and ASEAN

- Establish pharma function in OLIC
- Launch FSN-013
- Build WH S&M platform
- Accelerate expansion in China/ASEAN

North America
505(b)(2) launched by Fuji Pharma USA

- Define grand design by analyzing 505(b)(2) and the US market
- Commercialize Fuji Pharma USA
- Toyama qualified as global GMP



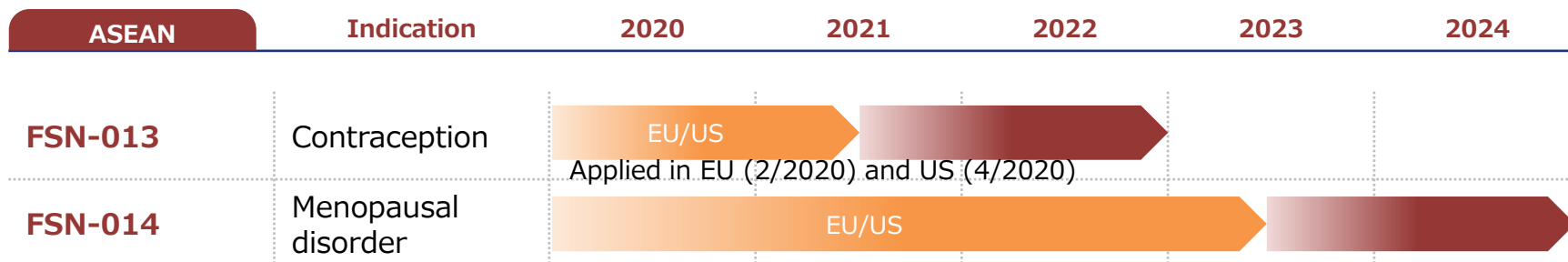
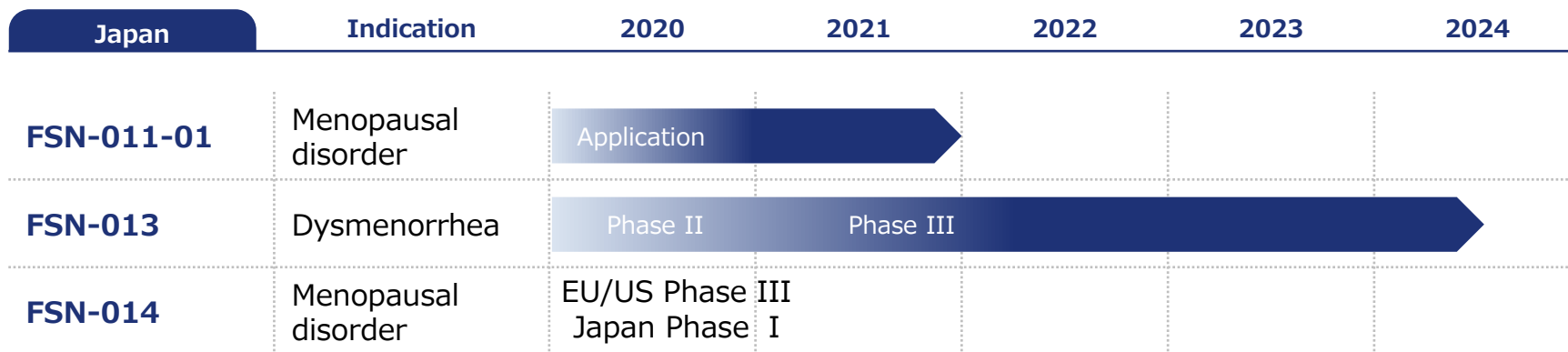
CMO ... Contract Manufacturing Organization

505(b)(2) ... An application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference

GMP ... Good Manufacturing Practice



Overseas ① Women's Healthcare – New Drug Pipeline



* Time table is shown as Fuji's target

Overseas ① Women's Healthcare – FSN-013 / Estetrol/Drospirenone

FSN-013

5th generation OC
New drug for dysmenorrhea

Overview

- Estetrol 15mg + Drospirenone 3mg
- Applied in Europe (EMA) and the US (FDA)

Characteristics

- Lower coagulant impact compared with existing products
- Lower interaction among drugs
- Expect better bleeding control
- Lower lipid impact
- Less likely to gain weight

Japan

Indication: Dysmenorrhea
Stage: Phase II
Launch: 2024 (target)

ASEAN

Indication: Contraception
Stage: Applied in US/EU
Launch: 2022 (target)

Japan (Phase II trial)

Trial: Open trial

Target: Healthy female adults

Term: 3 cycles

Dosage & Administration:

Cyclic: 1 cycle (28 days), once a day, 1 tablet orally for 24 consecutive days followed by placebo for 4 consecutive days

Continuous: 1 cycle, once a day, 1 tablet orally for 28 consecutive days

Result: Good pharmacodynamics outcomes for key evaluation items at the same level as overseas trial, and good tolerability

Overseas (Phase III trial)

Trial: Open trial

Target: Healthy female adults

Term : 52 cycles

Dosage & Administration:

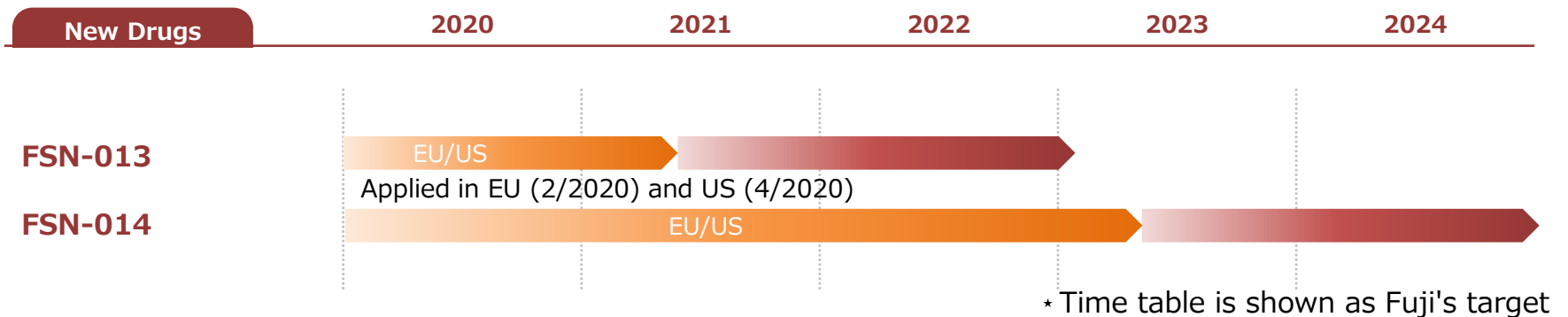
1 cycle (28 days), once a day, 1 tablet orally for 24 consecutive days followed by placebo for 4 consecutive days

Result: Good efficacy outcomes for contraception. Good safety outcomes for bleeding control and tolerability.

Overseas ⑥Asia / ⑦North America

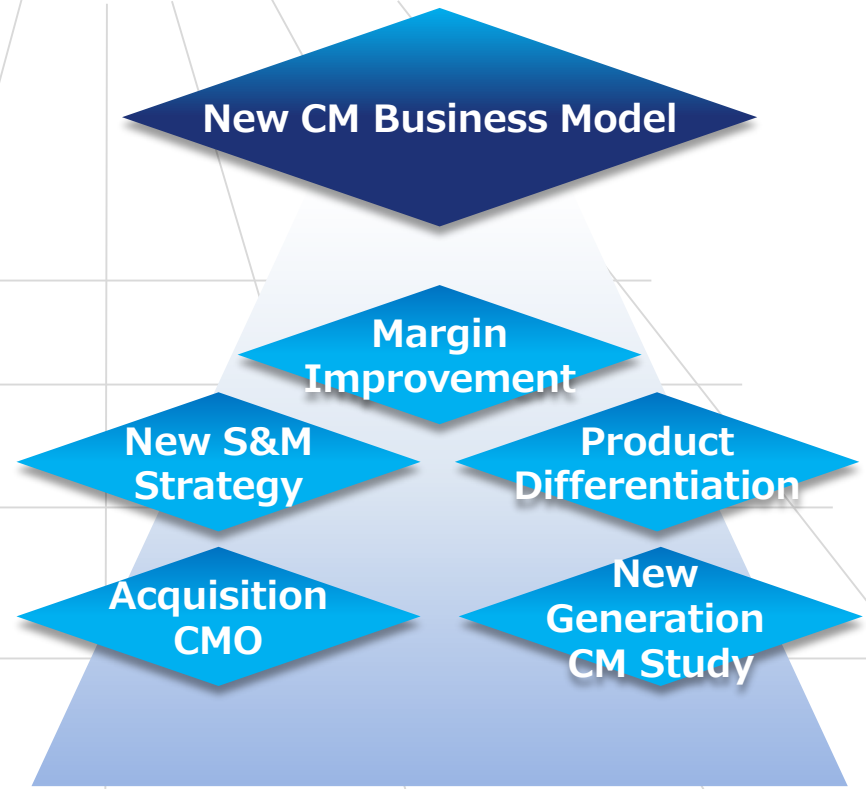
⑥Asia: OLIC to evolve into full pharma company

- Expand BD team and establish S&M function in ASEAN
- Short term product acquisitions to expand product portfolio
- Mid-to-long term licensing and bringing Fuji product in ASEAN



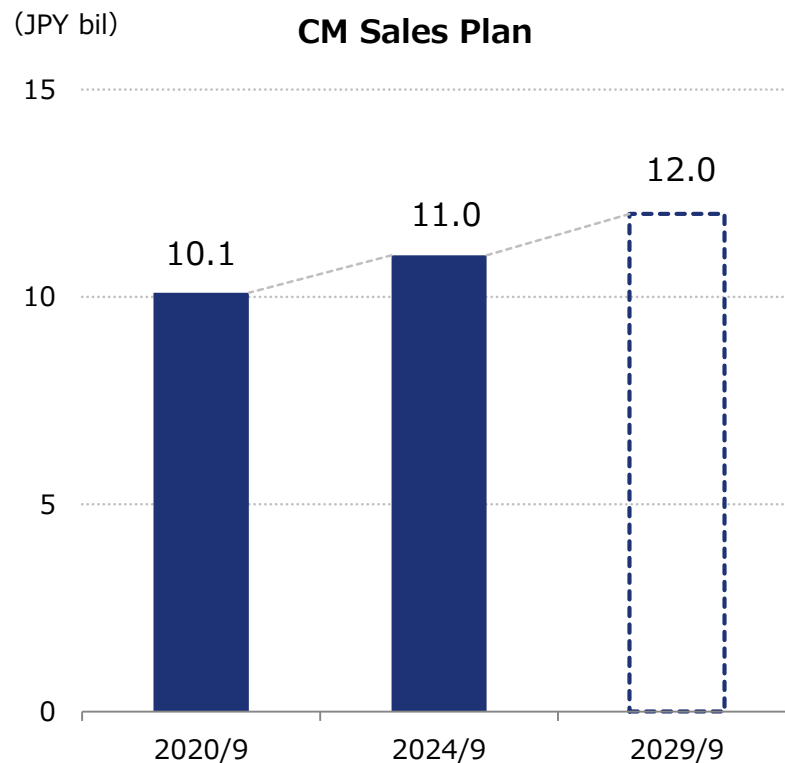
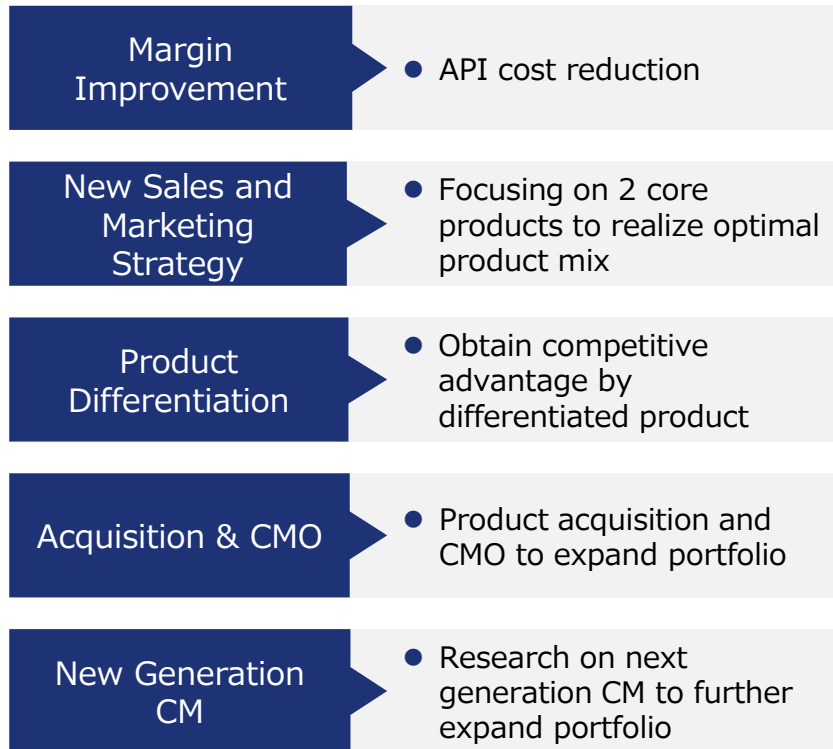
⑦North America: Enter into the US market

- CMO business development with tripolar GMP based in Toyama and multi-syringe production line
- Obtain 505(b)(2) approval leveraging formulation technology nurtured at Toyama R&D center
- M&A (European/US companies)



Contrast Media

Actions





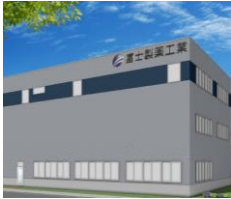
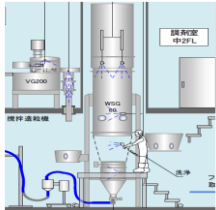
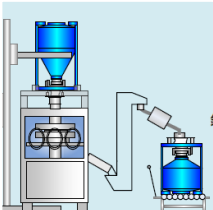


Chapter

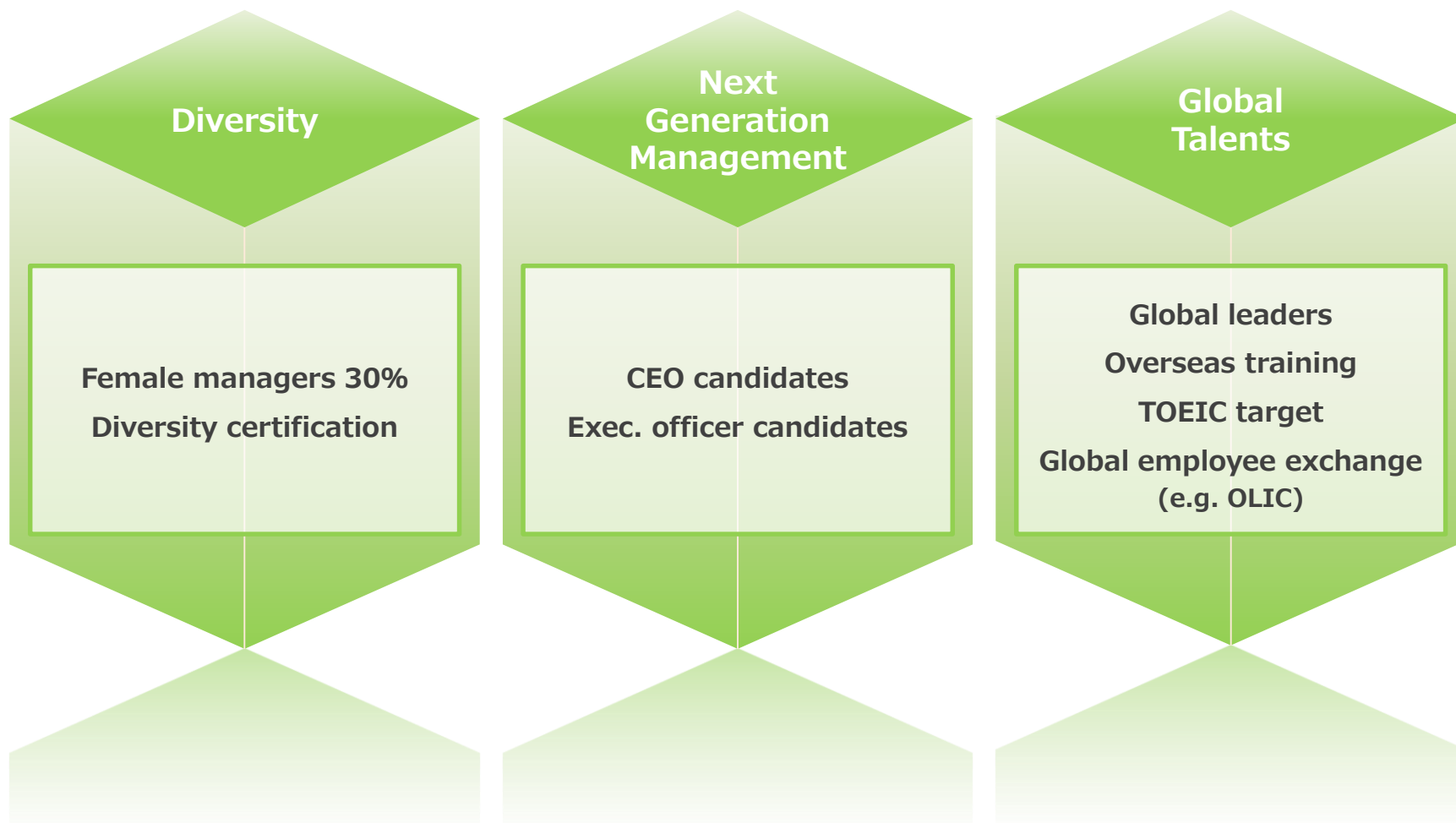
3

Foundation for Growth

Toyama Site Master Plan: ②Injection・③Hormone

Toyama SMP	Sustainable profit from CM business	Optimize injection line and enhance technology	Enhance hazard capacity	Global GMP	Sustainability	
		2019	2020	2021	2022	
<p>Adding ampule/vial line</p> <ul style="list-style-type: none"> Expand injection capacity Containing technology for HPA injectables PIC/S GMP 			<p>Ground Breaking</p> <p>---></p>	<p>PV</p>  		
<p>New management/welfare bldg.</p> <ul style="list-style-type: none"> More efficiency and capacity by integrating quality functions Data integrity 			<p>Ground Breaking (Dec)</p> <p>---></p>	<p>Completion (Aug)</p> 		
<p>New tablet building</p> <ul style="list-style-type: none"> Expand hormone capacity Containing technology for hormone products PIC/S GMP 			<p>Ground Breaking (Dec)</p> <p>-----></p>	<p>PV (Jun)</p>  		

Put People First



Integrating the world happiest company and social contribution



⑨ Sustainability – Notable Activities

Support performance of female athletes

Fuji Pharma contributes to well-being of women in the world. Supporting health condition of female athlete is important for them to show the best performance on the day they want. Fuji Pharma provides smart phone app to easily manage health and seek medical information from professional doctors.



Seminar held for Japan women's national field hockey team

Donated sanitizer to support fight against COVID-19

OLIC started to manufacture alcohol sanitizing gel and spray to support fight against COVID-19 in Thailand. OLIC products were donated to local hospitals and governments to protect health care workers and local officials from the disease.



OLIC donates alcohol gel to local hospitals and governments



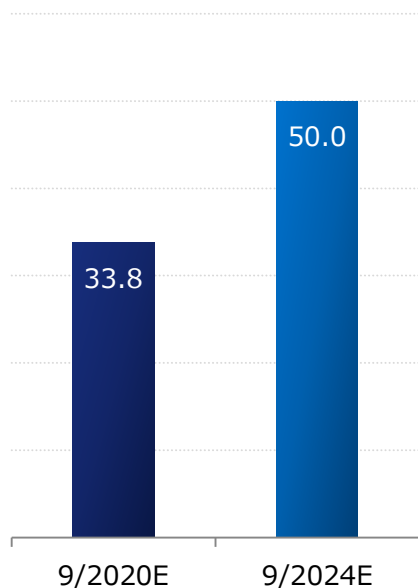
Chapter

4

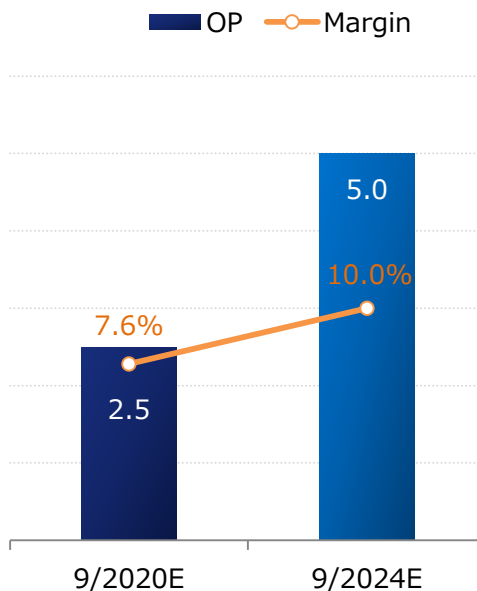
Financial Target

Key Financial Targets

Sales (JPY bil)



Operating Profit (JPY bil)



R&D·Capex (cumulative)

R&D

JPY **18.0** bil

Capex

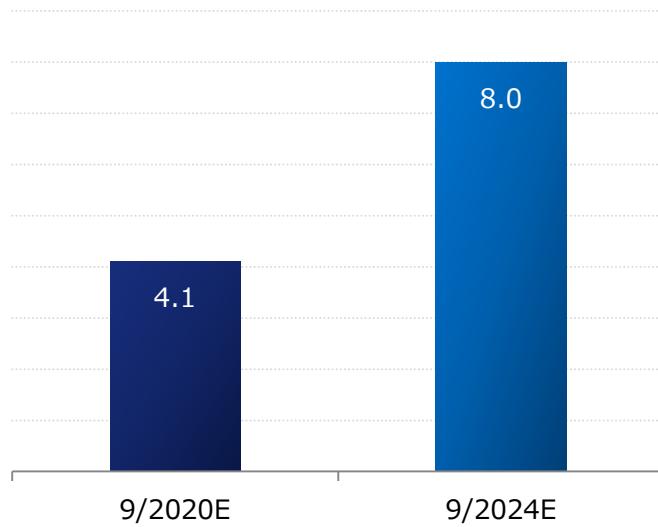
JPY **32.0** bil

* Total amount during MTP



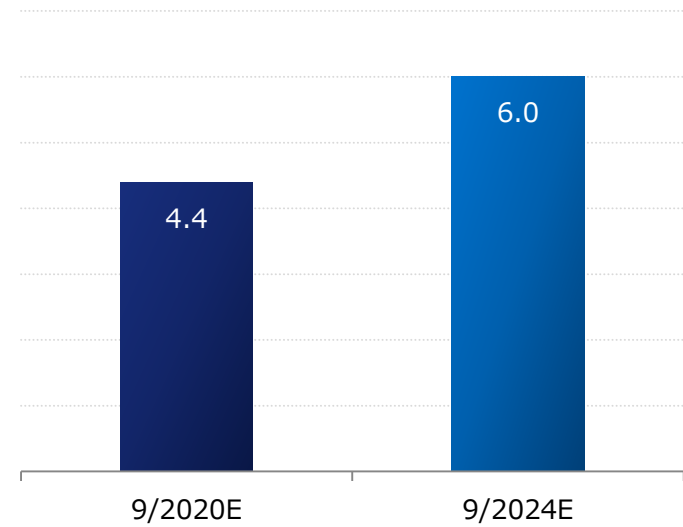
Key Financial Indices

ROE (%)



2029/9 Target 10-15%

ROA (%)

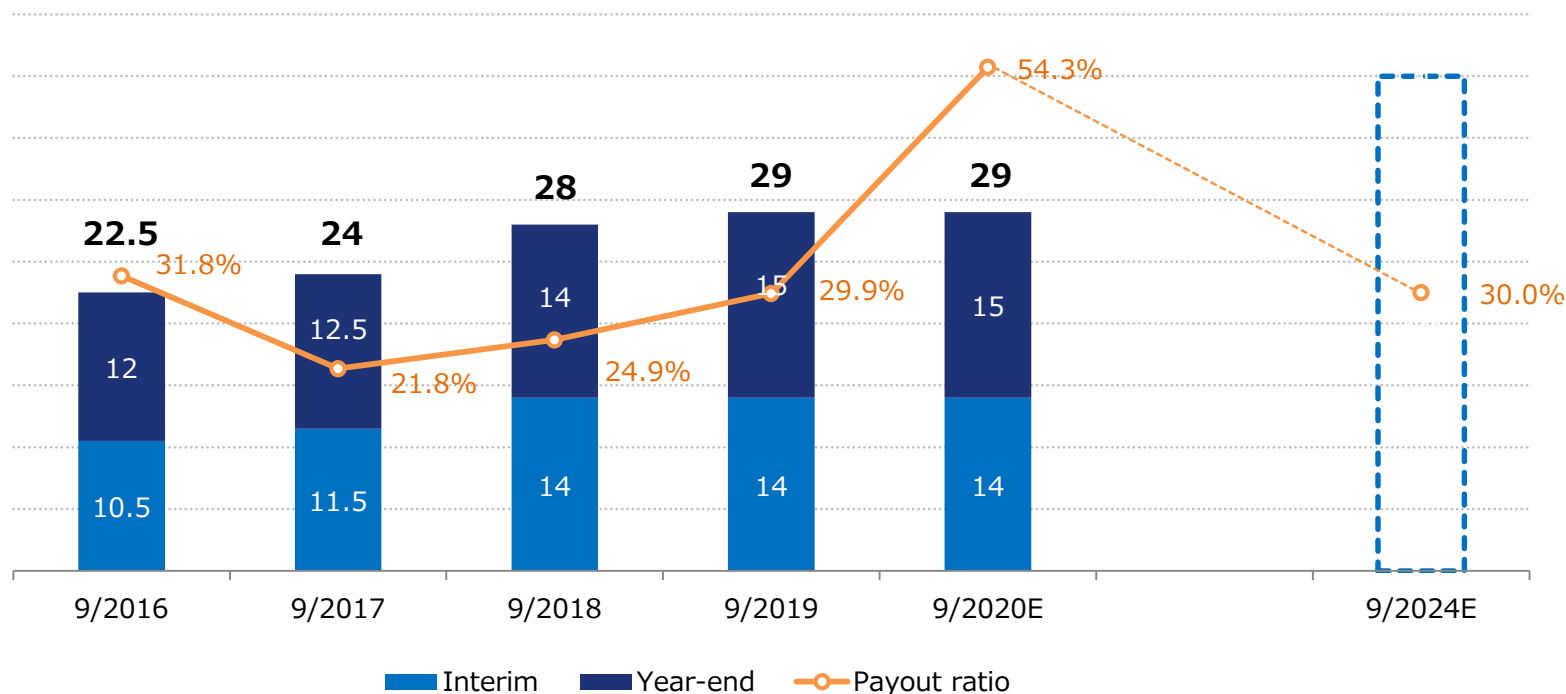


2029/9 Target 10-15%

Shareholder Return Policy

While continuing to invest to provide value, Fuji Pharma aim to achieve 30% payout ratio with stable dividends.

Dividend per share (JPY) / Payout ratio (%)



- On July 1, 2018, one common stock was split into 2 stocks. Dividend per share assumes current total outstanding shares.
- 9/2020E payout ratio is estimate at the beginning of fiscal year.



“Evolving Fuji”

Note on forecast and prospects

The financial forecasts and other projections provided in this presentation are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks.

Actual results may differ significantly from these forecasts for a number of reasons.

It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification.

Information in this presentation about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

Contact Information

Fuji Pharma Co., Ltd.
Corporate Planning Department

E - Mail : fsk_ir@fujipharma.jp

U R L : <https://www.fujipharma.jp/>