

COMPANY RESEARCH AND ANALYSIS REPORT

Fuji Pharma Co., Ltd.

4554

Tokyo Stock Exchange Prime Market

17-Jul.-2026

FISCO Ltd. Analyst

Tetsu Nakanishi



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Summary

Revised upward its forecasts and dividends for FY9/26

Fuji Pharma Co., Ltd. <4554> (hereafter, also “the Company”) is a Japanese pharmaceutical manufacturer primarily engaged in the development, manufacture, and sale of prescription pharmaceuticals. Established as a corporation in April 1965, the Company operates as a group, including overseas bases. The Company has maintained a strong focus on women’s healthcare since its founding. After initially expanding operations by providing generic drugs, recently it has established a position as a specialty pharma company centered on growth through new drugs, with women’s healthcare pharmaceuticals as its mainstay products, particularly hormone agents such as infertility treatments, oral contraceptives, and menopausal disorder treatments. The Company is currently listed on the Tokyo Stock Exchange Prime Market.

1. Overview of 1H FY9/26 results

In 1H FY9/26, driven by growth in the women’s healthcare business and the biosimilar business, net sales increased 23.3% year on year (YoY) to ¥29,716mn, operating profit rose 90.8% to ¥4,398mn, ordinary profit increased 92.9% to ¥4,263mn, while profit attributable to owners of parent declined 44.6% to ¥713mn. In addition to an improvement in gross profit margin from expanded sales of its high-gross-margin products, the recognition of some SG&A expenses was deferred to 2H, which also contributed to profit growth. Meanwhile, profit attributable to owners of parent declined to ¥713mn (down 44.6%). This was due to recording a valuation loss on shares of Alvotech hf., an Iceland-based partner in the biosimilar business. By business, the women’s healthcare business posted net sales of ¥13,152mn (up 28.0%), driving the Company’s overall growth. The menopausal disorder treatment, F-meno® Capsules (hereafter, “F-meno Capsules”), and the dysmenorrhea treatment, Alyssa® Combination Tablets (hereafter, “Alyssa Combination Tablets”), grew significantly. After prescription restrictions were lifted, adoption of Alyssa Combination Tablets expanded, and its share of new-patient prescriptions also increased. In the biosimilar business, net sales doubled to ¥1,854mn (up 102.6%), with Ustekinumab BS and the new product Aflibercept BS driving growth. Net sales in the global CMO business were also solid, rising 16.2% to ¥4,768mn, and in addition to expansion in domestic contract manufacturing, overseas contract manufacturing centered on its subsidiary, OLIC (Thailand) Limited (hereafter, OLIC) also continued stable growth.

2. FY9/26 forecasts

For FY9/26, the Company forecasts net sales of ¥59,250mn (up 14.7% YoY), operating profit of ¥6,120mn (up 22.6%), ordinary profit of ¥5,880mn (up 31.9%), and profit attributable to owners of parent of ¥2,240mn (down 25.3%). The Company revised forecasts upward at the 1Q results announcement. Meanwhile, the decrease in profit attributable to owners of parent was due to a one-off factor, that is, recording a valuation loss on shares of Alvotech. By business, the Company revised its full-year net sales forecast in the women’s healthcare business upward to ¥26,280mn (up 17.5%), expecting its mainstay products, F-meno Capsules and Alyssa Combination Tablets, to continue driving growth, and it also revised its full-year net sales forecast in the biosimilar business upward to ¥4,480mn (up 127.1%) on the back of contributions from Ustekinumab BS and Aflibercept BS, as well as the launch of new products expected to support growth. The Company expects its full-year net sales in the global CMO business to reach ¥8,500mn, forecasting steady growth in the contract manufacturing business at its Toyama Plant and its Thai subsidiary, OLIC. All three women’s healthcare business, biosimilar business, and global CMO business are growing, and progress on the Mid-Term Business Plan is regarded as on track.

Summary

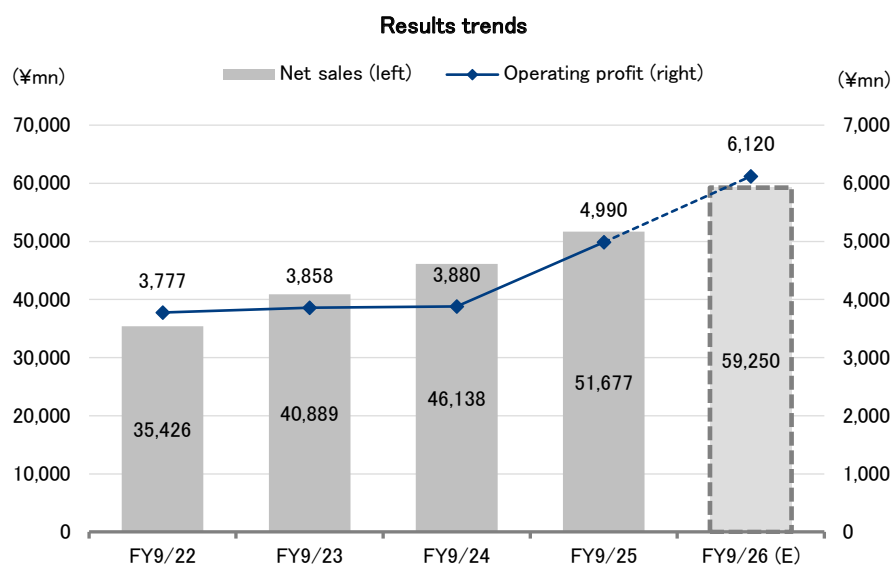
3. Medium- to long-term growth strategy

In the Mid-Term Business Plan (FY9/25 to FY9/29), the Company aims to achieve net sales of ¥80.0bn, operating profit of ¥10.0bn, and ROE of 10.0% in FY9/29. Positioning women's healthcare, biosimilar, and global CMO as the pillars of its growth strategy, the Company expects to achieve its plan, and progress has been steady through 1H FY9/26.

In its shareholder return policy, the Company has adopted a progressive dividend policy targeting a 30% dividend payout ratio based on after-tax operating profit. Dividend per share increased from ¥29.0 in FY9/20 to ¥45.5 in FY9/25, and for FY9/26, the Company also raised the full-year dividend from the initial forecast of ¥47.0 to ¥49.0. The Company's swift decision to increase the dividend in response to better-than-expected results indicates a stance of returning the benefits of profit growth to shareholders in a timely manner while continuing growth investments.

Key Points

- Achieved significant increases in both net sales and operating profit in 1H FY9/26
- Revised upward FY9/26 forecasts in 1Q. Expecting double-digit growth in operating profit and ordinary profit
- Targeting net sales of ¥80.0bn in FY9/29, anticipating 12% CAGR
- Revised upward the interim dividend forecast, providing timely shareholder returns in line with strong results



Source: Prepared by FISCO from the Company's financial results

Company profile

A highly unique specialty pharma company with a focus on women's healthcare

1. Company profile

The Company is a Japanese pharmaceutical manufacturer primarily engaged in the development, manufacture, and sale of prescription pharmaceuticals. Established in April 1965, the Company is headquartered in Sanbancho, Chiyoda-ku, Tokyo. It operates on a group basis including subsidiaries and overseas bases, and its consolidated employees totaled 1,760 as of the end of September 2025 (969 at Fuji Pharma Co., Ltd. and 791 at OLIC). Its shares were registered over-the-counter in June 1995, and it is currently listed on the Tokyo Stock Exchange Prime Market. Sales and distribution bases are located in major cities (Sapporo, Tokyo, Nagoya, Osaka, and Fukuoka), and the Company has a manufacturing plant and R&D center (Toyama Research and Development Center) in Toyama Prefecture. As part of global expansion, the Company has also established an overseas manufacturing and sales structure through its Thai subsidiary, OLIC, and it has expanded its business foundation centered on ASEAN.

Since its founding, the Company has consistently focused on women's healthcare. After initially expanding operations centered on generic drugs (generics) for about 45 years, the 2008 launch of the new dysmenorrhea treatment, Lunabell® Combination Tablets, marked a turning point, transforming the Company from a generic-drug manufacturer into a company handling new drugs. The Company also established its position as a specialty pharma company providing a wide range of pharmaceuticals tailored to women's life stages and centered mainly on hormone agents, including infertility treatments, oral contraceptives, menopausal disorder treatments, and dysmenorrhea treatments.

Currently, the Company operates in three business domains: women's healthcare business as its core, biosimilar business handling follow-on biologics, and contract manufacturing organization (CMO) business centered on the Toyama Plant and OLIC, and provides sustainable value to medical settings in Japan and overseas through deepening its expertise and expanding its business portfolio.

2. History

The Company originated from Fuji Pharmaceutical, founded in Toshima-ku, Tokyo in 1954. In 1959, it established a formulation plant in Mizuhashi-machi, Toyama Prefecture (now Mizuhashi District, Toyama City) and incorporated as Fuji Pharmaceutical Co., Ltd. It reorganized into a joint-stock company in 1965, and began full-scale development, manufacture, and sale of prescription pharmaceuticals. In 1974, it launched hormone agents for gynecological field and fully entered the women's healthcare field. Founder Seiichi Imai held the belief from the foundation to contribute to fields needed by many but underserved and viewed women's healthcare as embodying that philosophy. Though the women's healthcare market was small and highly specialized, involving products such as hormone agents, the Company adopted the approach of taking on the challenge precisely because there were unmet needs, and it worked on unique technology development and product supply. These efforts became the foundation for later uniqueness and expertise as a specialty pharma company. The Company subsequently expanded its business domains through launches like diagnostic agents (contrast media), and registered shares over-the-counter in 1995. In 2005, on its 40th anniversary, it renewed its corporate identity and rebuilt its corporate brand. In 2012, it acquired OLIC, a Thai pharmaceutical contract manufacturer, and made it a subsidiary to strengthen its overseas expansion and global CMO business. In 2013, the Toyama Research and Development Center was completed, as the Company expanded its R&D system.

Company profile

Currently, with the strengths in women's healthcare cultivated through long-term operation as its core and the biosimilar and global CMO businesses as growth pillars, the Company has evolved into a specialty pharma company combining expertise and international competitiveness that is listed on the Tokyo Stock Exchange Prime Market.

Business overview

Building unique competitive advantages through a focus on women's healthcare and a commitment to new drug development

1. Women's healthcare

Women's healthcare is the Company's core business, and in its Long-Term Vision 2035, it states its commitment to "always focusing on creating new value to women's healthcare," positioning sustainable value creation centered on this domain as the foundation of its growth. In Japan, treatment rates for conditions such as dysmenorrhea and menopausal disorders are lower than in Europe and the US, leaving substantial room for market expansion. According to estimates by the Ministry of Economy, Trade and Industry*, economic losses attributable to women's health issues are about ¥600.0bn for menstruation-related issues and about ¥1.9tn for menopause-related issues, making this a market in which both the resolution of social issues and market expansion are expected.

* Ministry of Economy, Trade and Industry, "Estimation of Economic Loss Due to Women's Health Issues and the Necessity of Health Management" (February 2024)

The Company positions the dysmenorrhea treatment, Alyssa Combination Tablets, as a growth driver and expects net sales to reach ¥10.0bn in 2029. Now in its second year on the market, the product has been growing faster than planned, and its prescription share among new patients with dysmenorrhea has reached 15%. In addition, the expansion of the dysmenorrhea market—which is estimated at approximately ¥73.0bn based on the NHI drug price of Alyssa Combination Tablets—is also providing a tailwind for the product. Furthermore, the menopausal disorder treatment, F-meno Capsules, is also growing, supported by the expansion of the hormone replacement therapy (HRT) market. The Company is expanding market share by leveraging digital promotion through collaboration with approximately 90 dedicated women's healthcare medical representatives (MRs) and M3, Inc. <2413>, and promoting disease awareness initiatives in partnership with major media outlets.

The Company has products including approximately 40 items. By comprehensively covering women's life stages—through areas such as dysmenorrhea, contraception, menopause, and infertility—it aims to establish itself as a top brand in women's healthcare both in Japan and overseas. In addition, the Company plans to roll out Nextstellis (containing the same active ingredients as Alyssa Combination Tablets) to the ASEAN region. The product is already sold in Thailand by its Thai subsidiary, OLIC.

The Company announced on February 6, 2026 that it had concluded a strategic collaboration agreement in the gynecology field with Gedeon Richter Plc. (headquartered in Hungary). The aim is to accelerate the expansion of its development pipeline for promising new drug candidates, including an antibody for the treatment of endometriosis that could become first-in-class and is among the Company's development candidates.

2. Biosimilar

The biosimilar business is the Company's next-generation growth business. Biosimilars are follow-on products that are equivalent in quality, efficacy, and safety to reference biopharmaceuticals, and their adoption is being promoted as a national policy from the perspective of curbing healthcare costs.

The Company is one of Japan's leading biosimilars companies, having obtained approval and launched five products in Japan. Filgrastim BS, one of the Company's existing products used to help restore white blood cell counts reduced by anticancer drugs, has been on the market for 13 years and, despite a substantial decline in drug prices, has remained commercially viable and ensured a stable supply. In addition, the psoriasis treatment, Ustekinumab BS, launched in 2024, has leveraged its first-to-market advantage as a follow-on product to achieve a 96% share of adopting medical institutions (the Company's estimate). Furthermore, the Company is expanding its lineup with new products, including the age-related macular degeneration treatment, Aflibercept BS, the rheumatoid arthritis and other indications treatment, Golimumab BS, and the bone lesions treatment, Denosumab BS.

In addition, through a strategic partnership with Alvotech <ALVO>, a biotechnology company, the Company is expanding its development pipeline, including antibody therapeutics, and aims to enhance development speed and competitiveness. Going forward, the Company will also consider partnerships with overseas partners other than Alvotech, conducting candidate selection and building its development strategy while assessing market penetration by active ingredient and the expansion of indications. The biosimilar business addresses the social issue of rising healthcare costs and enables high-quality medical care, serving as an important pillar supporting medium- to long-term growth.

3. Global CMO

The global CMO business provides contract pharmaceutical manufacturing services for Japanese and overseas pharmaceutical companies and is a strategic domain responsible for stabilizing the revenue base and expanding internationally. Centered on the Toyama Plant, the Company has accumulated a track record in contract manufacturing of formulations that require specialized manufacturing equipment and production technologies, such as hormone agents and injectables. Also, leveraging OLIC, it has built a global production network with its dual-site structure of Toyama and Thailand. OLIC is one of ASEAN's leading contract manufacturing organization companies, with more than 40 years of history and a track record of business with numerous global pharmaceutical companies. This business not only expands sales through contract manufacturing, but also plays a role in acquiring cutting-edge manufacturing technology and quality control expertise through the production of other companies' products, thereby accumulating intangible assets. The Company currently has surplus production capacity, allowing it to build up new contract orders without large-scale additional investment.

Going forward, by expanding into high value-added fields including biosimilars and highly pharmacologically active formulations, the Company is aiming to evolve into a full-scope contract development and manufacturing organization (CDMO) that provides development, manufacturing, and quality assurance comprehensively. The global CMO business serves as an important business foundation that supports the Company's growth and earnings stability.

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Results trends

Achieved significant increases in both net sales and operating profit in 1H FY9/26

1. Results trends for 1H FY9/26

In 1H FY9/26, net sales were ¥29,716mn (up 23.3% YoY), operating profit was ¥4,398mn (up 90.8%), ordinary profit was ¥4,263mn (up 92.9%), and profit attributable to owners of parent was ¥713mn (down 44.6%). The operating profit margin also improved significantly from 9.6% in 1H FY9/25 to 14.8%. Driven primarily by the women's healthcare and biosimilar businesses, profit was lifted by expanded sales of new products and an improved gross profit margin resulting from a more favorable product mix (higher proportion of its high-gross-margin products), while the deferral of certain SG&A expenses to 2H also raised profit.

Meanwhile, the significant decline in profit attributable to owners of the parent was not caused by deterioration in business; the main factor was the recognition of a ¥3,519mn valuation loss on investment securities as an extraordinary loss following a decline in the share price of Alvotech, the global licensor for the biosimilar business. Note that this valuation loss is a non-cash, one-off loss, and the Company has left its full-year forecasts unchanged.

Overview of 1H FY9/26 results

	1H FY9/25		1H FY9/26		YoY	
	Results	Composition/ vs. net sales	Results	Composition/ vs. net sales	Change	Change (%)
Net sales	24,095	-	29,716	-	5,621	23.3%
Women's healthcare	10,278	42.7%	13,152	44.3%	2,874	28.0%
Biosimilar	915	3.8%	1,854	6.2%	939	102.6%
Global CMO	4,102	17.0%	4,768	16.0%	666	16.2%
Other	8,799	36.5%	9,940	33.4%	1,141	13.0%
Operating profit	2,305	9.6%	4,398	14.8%	2,093	90.8%
Ordinary profit	2,209	9.2%	4,263	14.3%	2,054	92.9%
Profit attributable to owners of parent	1,287	5.3%	713	2.4%	-574	-44.6%

Source: Prepared by FISCO from the Company's financial results and results briefing materials

2. Results trends by domain

The Company operates in a single pharmaceutical business segment but is engaged in three business domains: women's healthcare, biosimilar, and global CMO.

(1) Women's healthcare

Net sales in the women's healthcare business were ¥13,152mn (up 28.0% YoY), continuing to drive the Company's net sales growth. Among the core products, the menopausal disorder treatment, F-meno Capsules, rose sharply to ¥3,053mn (up 69.4%), while Alyssa Combination Tablets surged to ¥1,361mn (up 504.9%). Adoption of Alyssa Combination Tablets has accelerated since the lifting of prescription restrictions in December 2025. Both the menopausal disorders and dysmenorrhea therapeutic areas have substantial room for market expansion, strengthening their presence as the Company's growth drivers.

Results trends

(2) Biosimilar

Net sales in the biosimilar business were ¥1,854mn (up 102.6% YoY), representing a doubling year on year. Ustekinumab BS maintained high growth and recorded ¥271mn (up 185.3%), and net sales of new products, including Aflibercept BS launched in January 2026, were ¥776mn. Although Filgrastim BS remained flat due to the impact of drug price revisions, the launch of multiple new products is advancing the expansion of the Company's business portfolio. In addition, the biosimilar business is preparing the market launch of Golimumab BS and Denosumab BS with high expectations for medium-term growth.

(3) Global CMO

Net sales in the global CMO business were ¥4,768mn (up 16.2% YoY). Domestic contract manufacturing rose to ¥2,637mn (up 30.2%), showing strong growth, while overseas contract manufacturing, mainly at OLIC, also remained solid. The business is positioned as one of the growth strategies in the Mid-Term Business Plan, and the Company views its progress as generally in line with expectations. In addition to securing stable earnings through pharmaceutical contract manufacturing, the business has an aspect on the accumulation of manufacturing technology and quality control expertise, and continues steady growth as the business foundation that supports women's healthcare and biosimilar.

■ Outlook

Revised upward FY9/26 forecasts in 1Q. Expecting double-digit growth in operating profit and ordinary profit

1. FY9/26 forecasts

For FY9/26, the Company forecasts net sales of ¥59,250mn (up 14.7% YoY), operating profit of ¥6,120mn (up 22.6%), ordinary profit of ¥5,880mn (up 31.9%), and profit attributable to owners of parent of ¥2,240mn (down 25.3%). At the 1Q results announcement in February 2026, the Company revised its full-year forecast, citing faster-than-expected growth in key products in women's healthcare and biosimilar businesses, and an improvement in the product mix driven by expanding sales of its high-gross-margin products. As a result, net sales were revised upward from ¥57,490mn to ¥59,250mn, and operating profit from ¥5,520mn to ¥6,120mn. Meanwhile, the Company revised downward profit attributable to owners of parent from ¥3,810mn to ¥2,240mn due to recording a valuation loss on shares of Alvotech, the partner in the biosimilar business. However, this is not due to a decline in the core business's earning power, but rather reflects the impact of a one-off valuation loss on investment securities.

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Outlook

FY9/26 forecasts

(¥mn)

	FY9/25		FY9/26				YoY	
	Results	Composition/ vs. net sales	Initial forecast	Composition/ vs. net sales	Revised forecast	Composition/ vs. net sales	Change	Change (%)
Net sales	51,677	-	57,490	-	59,250	-	7,573	14.7%
Women's healthcare	22,372	43.3%	25,280	44.0%	26,280	44.4%	3,908	17.5%
Biosimilar	1,973	3.8%	3,720	6.5%	4,480	7.6%	2,507	127.1%
Global CMO	8,342	16.1%	8,500	14.8%	8,500	14.3%	158	1.9%
Other	18,989	36.7%	19,990	34.8%	19,990	33.7%	1,001	5.3%
Operating profit	4,990	9.7%	5,520	9.6%	6,120	10.3%	1,130	22.6%
Ordinary profit	4,459	8.6%	5,240	9.1%	5,880	9.9%	1,421	31.9%
Profit attributable to owners of parent	3,000	5.8%	3,810	6.6%	2,240	3.8%	-760	-25.3%

Source: Prepared by FISCO from the Company's financial results and results briefing materials

2. Forecasts by domain

(1) Women's healthcare

Expected net sales in the women's healthcare business are ¥26,280mn (up 17.5% YoY), which have been revised upward by ¥1,000mn from the initial forecast at the 1Q results announcement. The growth drivers are F-meno Capsules and Alyssa Combination Tablets. Sales of F-meno Capsules remain strong on the back of expansion in the menopausal disorder market and the suspension of supply of competing products, and prescriptions for Alyssa Combination Tablets are also expanding following the lifting of prescribing restrictions. In particular, as the Alyssa Combination Tablets has entered its second year on the market and its prescription share among new patients continues to rise, the women's healthcare business is expected to remain the Company's largest growth driver and continue to propel results.

(2) Biosimilar

Expected net sales in the biosimilar business are ¥4,480mn (up 127.1% YoY), which have been revised upward by ¥760mn from the initial forecast at the 1Q results announcement. In addition to the mainstay Ustekinumab BS, Aflibercept BS, for which sales began in January 2026, is expected to contribute materially. In addition, preparations for the NHI drug price listing and launch of Golimumab BS and Denosumab BS are underway, further expanding the product lineup. In the biosimilars market, first-to-market companies tend to capture a high market share; the Company's three marketed products were first to market*, and it expects its approved products to also be first to market. Therefore, the business is expected to be a powerful growth engine under the Mid-Term Business Plan, with earnings expansion anticipated going forward.

* The first product launched ahead of others in the market is referred to as "first to market." Products entering later are referred to as second- or third-to-market.

(3) Global CMO

Expected net sales in the global CMO business are ¥8,500mn (up 1.9% YoY), unchanged from the initial forecast. This business is a contract manufacturing business centered on OLIC, and the current order environment remains solid. While not a high-growth area such as women's healthcare or biosimilar, it plays an important role in generating stable revenue and accumulating technology and quality control expertise through business with global pharmaceutical companies. The Company positions the global CMO business as one of the growth strategies in the Mid-Term Business Plan and expects steady growth.

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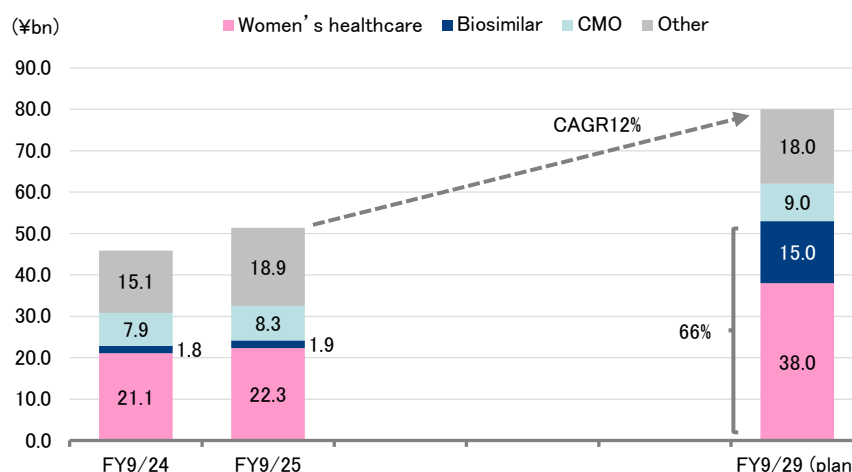
Medium- to long-term growth strategy

Targeting net sales of ¥80.0bn in FY9/29, anticipating 12% CAGR

The Company has formulated Long-Term Vision 2035 of “Always focusing on creating new value to women’s healthcare and contributing to society where everyone can enjoy well-being” as its desired state in 10 years. The Mid-Term Business Plan (FY9/25 to FY9/29) is positioned as the first five years toward achieving this vision, aiming for sustainable growth and enhanced corporate value. The core of the growth strategies consists of three initiatives: enhancing domestic and international presence through expansion of women’s healthcare, full-scale expansion of the biosimilar business, and establishing a stable earnings base through the global CMO business. In the women’s healthcare business, the Company aims to achieve net sales of ¥38.0bn in 2029 through sales expansion of the new drug, Alyssa Combination Tablets, and overseas expansion centered on Thailand. In the biosimilar business, the Company plans to grow net sales to ¥15.0bn in 2029 by promoting sales of four products partnered with Alvotect, including Ustekinumab BS. The global CMO business is responsible for generating stable earnings through the contract manufacturing business that leverages the Toyama Plant and its Thai subsidiary, OLIC.

The Company positions the women’s healthcare and biosimilar businesses as the dual wheels of its growth and aims to build a business portfolio in which both businesses account for about two-thirds of sales by 2029. Through these initiatives, the Company aims to achieve net sales of ¥80.0bn (assuming a CAGR of 12% from FY9/25), operating profit of ¥10.0bn, and ROE of 10.0% for FY9/29.

Net sales targets by business domain in the Mid-Term Business Plan



Source: Prepared by FISCO from the Company's results briefing materials and Mid-Term Business Plan

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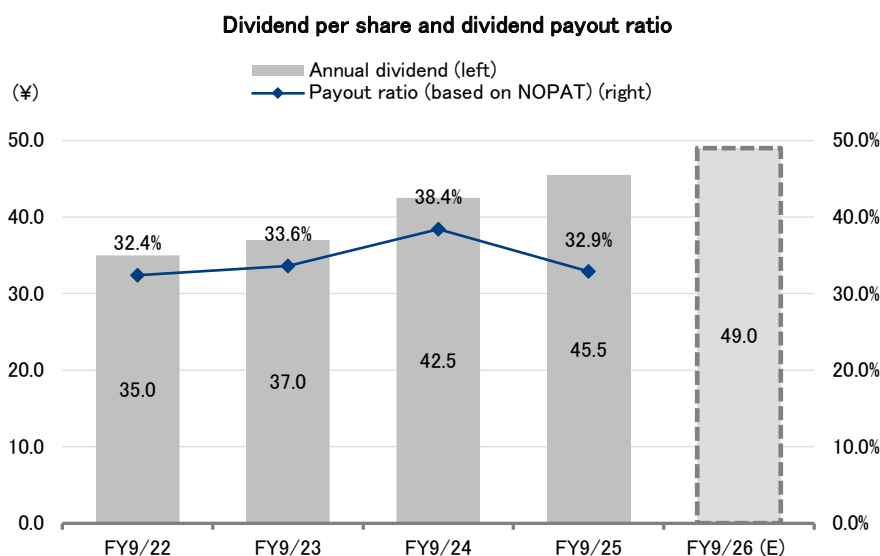
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Shareholder return policy

Revised upward the interim dividend forecast, providing timely shareholder returns in line with strong results

The Company targets a dividend payout ratio of 30% based on operating profit after tax under its dividend policy and adopts a progressive dividend policy. It is promoting a capital policy that emphasizes balancing growth investment and shareholder returns. Indeed, the dividend per share has consistently increased from ¥29.0 in FY9/20 to ¥45.5 in FY9/25, and the Company has steadily expanded shareholder returns in line with profit growth. The Company has also maintained its dividend payout ratio in the 30% range, indicating a shareholder return policy that balances stability and growth. Furthermore, for FY9/26, the Company decided to increase the annual dividend from the initially planned ¥47.0 (interim ¥21.0, year-end ¥26.0) to ¥49.0 (interim ¥23.0, year-end ¥26.0).

The key feature of this dividend increase is that, following an upward revision to forecasts at the 1Q results announcement, a prompt decision was made during the fiscal year to increase the interim dividend. This is seen as reflecting the management's policy of timely returning to shareholders the benefits of better-than-expected results. While continuing proactive growth investments in the women's healthcare and biosimilar businesses, the Company is also working to expand shareholder returns in line with profit growth.



Source: Prepared by FISCO from the Company's financial results and New Mid-Term Business Plan presentation materials

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■ For inquiries, please contact: ■

FISCO Ltd.

5-13-3 Minami Aoyama, Minato-ku, Tokyo, Japan 107-0062

Phone: 03-5774-2443 (IR Consulting Business Division)

Email: support@fisco.co.jp