FujiPharma

https://www.fujipharma.jp/

Fuji Pharma Co., Ltd.

CORPORATE REPORT 2021

Fuji Pharma Co., Ltd.

■ **For IR inquiries, please contact**

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Working to bring smiles to the faces of women for half a century

Since its foundation in 1965,
Fuji Pharma has valued pride in being involved in people's lives,
joy and happiness in serving people, and gratitude to the people,
and placed the highest priority on contributing to the people's lives around the world.
Fuji Pharma will continue putting its desire to contribute
to the healthy lives of people around the world first,
taking on challenges, and achieving what only Fuji Phama can do.

Corporate Philosophies

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 pharmaceutical drugs for medical care.

Virtues as Fuji Pharma's values

We value the concept of virtues, which originates from the Chinese classics, in our corporate management.
We have defined the 7 virtues and 19 associated qualities shown below and adopted them for personnel evaluation.

Propriety	Righteousness	Determination	Wisdom	Benevolence	Moderation	Sincerity
Respectful communication, Listening, Respect, The 5S's and Posture	Justice, Honoring commitments, respecting rules	Mission, Concentration, Challenge	Impartiality, Self control (Discipline), Private discipline	Generosity and tolerance, Mercy and empathy, Non-intrusiveness	Study to improve self, Essentiality, Fairness and balance	Conviction

More information about the virtues can be found here ⟹ P. 3

Contents

Editorial Policy

This Corporate Report is published to make Fuji Pharma's business activities, management and values for the contribution to society and the environment better and more plainly understandable by all stakeholders. This publication pertains basically to the fiscal year ended September 30, 2020 (from October 1, 2019 to September 30, 2020). (However, it contains some information from October 2020 and later.)
This Corporate Report includes information on drugs, including those under development. However, this information is not intended for advertising or medical advisory purposes.

Aiming for sustainable growth through the creation of a virtuous cycle of contribution and growth

Since its foundation in 1965, Fuji Pharma has taken pride in being involved in people's lives and prized the joy and happiness of serving people and appreciation for people, and we have given first priority to contributing to the lives of people around the world in line with our corporate philosophies: "We help people lead healthy lives by offering excellent pharmaceuticals" and "Our corporate growth is proportional to our personal growth."

In addition to our corporate philosophies, we also value the idea of "virtue." In general, the word virtue is often connected to morality. However, we believe that it means to do one’s best, thoroughly, for the sake of others. Our definition of a person of virtue is therefore a person who does his / her best for others and is pleased about others' happiness and success from the bottom of his or her heart. We incorporate this idea in our personnel evaluation system. We hope our employees will always be aware of what they are working for and translate the work they do into their own personal growth.

By continuing to contribute to people's healthy lives through the provision of even better pharmaceuticals we will endeavor to enhance our own personal opportunities to grow. Seizing such growth opportunities, we as individual employees will produce continue to accumulate the high quality and high quality work, everyday, will drive Fuji Pharma's corporate growth. Our growth as a company will then reap rewards for people all over the world. We have been given the responsibility of creating such a virtuous cycle and continuing to contribute to the happiness of people around the world.
With the shared goal of continuing to help people around the world lead healthy lives, we aspire to make the Fuji Pharma Group deserving of even greater trust and support by constantly tackling difficult problems and accomplishing things only we can do.

We look forward to your continued understanding and support.

May 2021

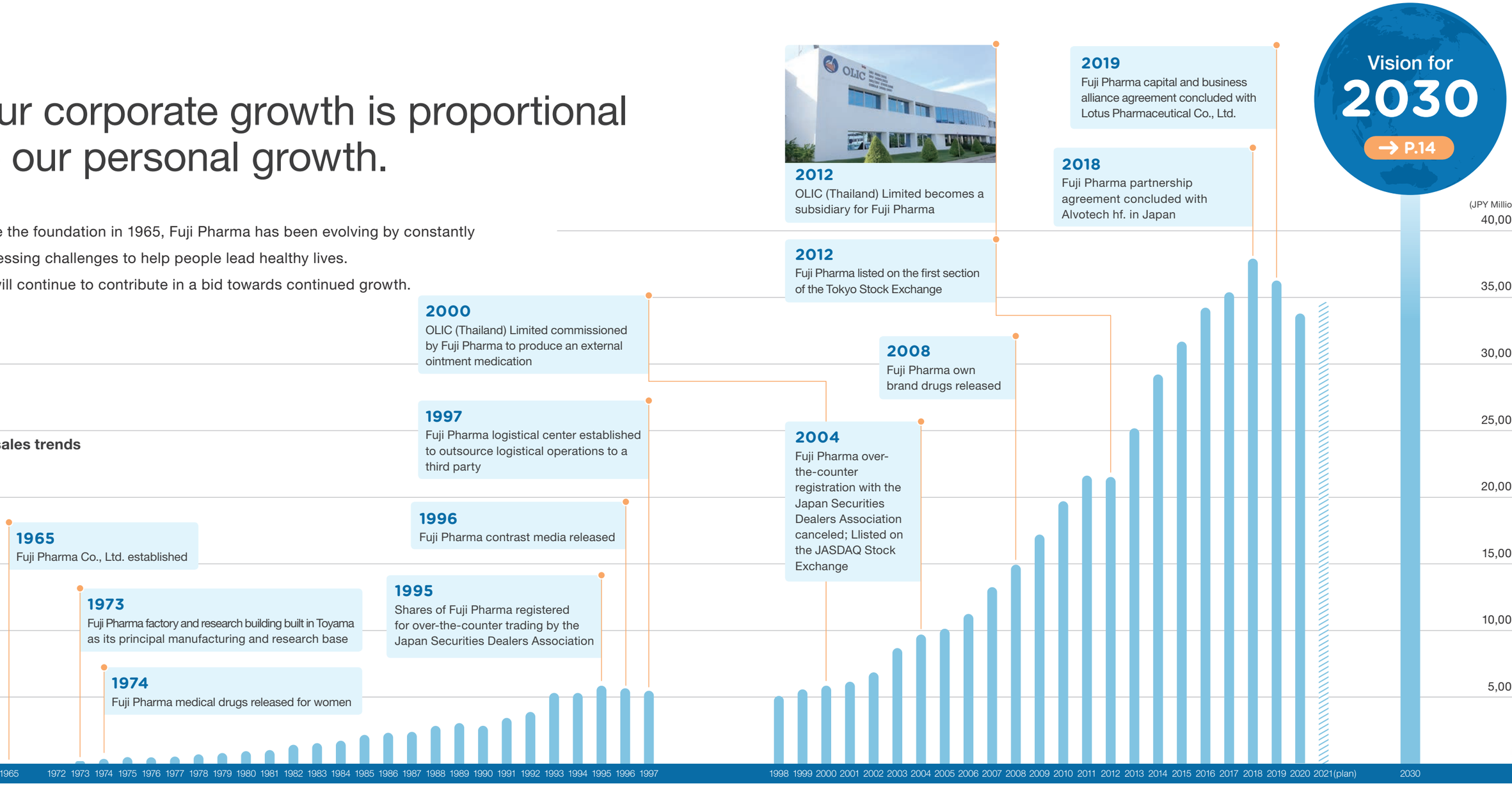
Chairman & Representative Director
Hirofumi Imai

President & CEO
Takayuki Iwai

Our corporate growth is proportional to our personal growth.

Since the foundation in 1965, Fuji Pharma has been evolving by constantly addressing challenges to help people lead healthy lives.
We will continue to contribute in a bid towards continued growth.

Net sales trends



Principal Products

GE Generic Drug ND New Drug BS Biosimilar

Non-ionic contrast medium for urography and angiography IOPAMIDOL injection F

Non-ionic contrast medium IOHEXOL injection F

LUNABELL® Tablets LD for dysmenorrhea

Filgrastim BS Injection F G-CSF

LUNABELL® Tablets ULD for dysmenorrhea

UTROGESTAN® Vaginal Capsules natural progestational hormone agent

DIENOGEST tablets F for endometriosis and adenomyosis-associated pain improvement

LEVONORGESTREL tablets F for emergency contraception

Fuji Pharma's Value Creation Process

Fuji Pharma has constructed a one-stop system from research and development to sales to answer the needs of as many patients and medical professionals as possible.
We will continue our constant growth and expansion to realize our principle of helping people around the world by offering excellent pharmaceuticals.

Social Needs and Challenges

Stable supply of pharmaceuticals

Improvement in medical care quality

Medical expenses reduction

Prolongation of healthy life extension

Women empowerment

Fuji Pharma's Business Activities

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.

Fuji Pharma's Value Chain

Patients
Medical Institutions
Drug Wholesalers

Sustainability

Human Resources

Foundations for Corporate Value

Products and Services

Women's Healthcare

Fertility drugs

Drugs for dysmenorrhea

LiLuLa – a website supporting women in health

Acute Medical Care

Non-ionic contrast medium for urography and angiography

Biosimilars

Value Created

Social Value

Contribution to the continued growth of society through medical care

Improvement in medical care quality through high-quality pharmaceuticals

Improvement in patients quality of life

Suppression of rise in national medical expenses

Decline in personal economic burden

Economic Value

Fiscal year ended September 30, 2020

Net sales	JPY 33.793 Million
Operating margin	9.3%

Vision

Mid-Term Business Plan
Financial Targets for FY 9/2024

Net sales	Operating margin
JPY 50 Billion	10%

Theme of the Mid-Term Business Plan: Fuji らしくを あたらしく

Vision for 2030
Financial Targets for FY 9/2029

Net sales	Operating margin
JPY 100 Billion	20%

Evolving Fuji
Strengthening our business base for the future, aiming for sustainable growth.

President & CEO Takayuki Iwai

A year of steady progress towards achieveing our Mid-Term Business Plan (FY9/2020-9/2024)

I am Takayuki Iwai, President & CEO. Over the past year and a half, since becoming president, our society as a whole has faced a massive transformation due to COVID-19 pandemic. The past eighteen months has also caused major changes in the ways things are done on a global scale. We have also dramatically changed the way we work, increasing working from home as much as possible, due to the effects of COVID-19 pandemic.
Meanwhile, if we turn our attention to the business environment surrounding pharmaceuticals, measures to curb medical expenses, which are squeezing the Japan's finances, having become even tougher, with NHI prices set to be revised annually from fiscal year 2021, instead of every two years as before. On the other hand, given that expansion of NHI coverage for infertility treatment is under consideration, we believe there are now even more opportunities for us now to "help people lead healthy lives by offering excellent pharmaceuticals" in line with our corporate philosophy. Based on this corporate philosophy, we plan to continue researching and developing new drugs to expand our development pipeline for the upcoming few years. We also intend to expand our manufacturing capacity to maintain a stable supply of safe and secure drugs.
Also, since the beginning of this year, generic drug manufacturers have been ordered by the competent authorities to suspend their businesses, one after another. We consider such issues to be major incidents that undermine trust in the entire pharmaceutical industry and we do not see them as someone else's problem. As a company involved in the manufacture of pharmaceuticals, these incidents have made us sit up straight and strengthened our resolve to do our job seriously.

In the fiscal year ended September 30, 2020, we achieved our initial plan despite the effects of the COVID-19 pandemic.

Our consolidated operating profit for the fiscal year ended September 30, 2020 was 3,139 million yen. Though 75.2% of the level a year earlier, this result was far higher than planned, representing 122.1% of the forecast level. The year-on-year decline in profit is mainly attributable to decreased sales, reflecting the release of a generic version of LUNABELL® tablets, our branded mainstay drug for the treatment of dysmenorrhea, and the impact of expiration of an agreement concerning branded contrast media. However, we managed to keep the decline in sales caused by the effects of the COVID-19 pandemic to a minimum and succeeded in achieving higher profit than forecast.
These effects of the COVID-19 pandemic include fewer examinations using contrast media under the state of emergency from April through May 2020 and hesitancy to seek infertility treatment after the Japan Society for Reproductive Medicine recommended patients delay infertility treatment, and the overall sales decline was due to decreased sales of products in these domains.

The pharmaceutical industry continues to face a challenging business environment but the environment surrounding women's healthcare is changing.

Japan's pharmaceutical industry continues to face an increasingly difficult business environment, with tougher requirements for price premiums to promote the development of new drugs and eliminate off-label use and the approval of a tough pricing system to gradually reduce long-listed drug prices down to the generic level, in addition to the "off-year" NHI price revisions mentioned earlier.
On the other hand, changes in the environment surrounding women's healthcare are starting to emerge, notably moves by the government to include infertility treatments in NHI coverage. Public interest in women's healthcare issues is also growing, with Femtech attracting increasing attention. We believe that if, alongside this growing interest, society evolves so that women who have struggled to get treatment in the past are able to access treatment, then we, as a specialist in the women's healthcare field, will have more opportunities to support a greater number of women.

Formulation of Mid-Term Business Plan (FY9/2020-9/2024) for achieving the Vision for 2030

In 2019, when I became president, we developed the "Vision for 2030," clearly setting out where we wanted to be 10 years from then. Under this Vision for 2030, our aim is to realize three goals: "contributing to well-being of women in the world"; "expanding our business to Global Market from Toyama" and "integrating the world's happiest company and social contribution".
To ensure realization of the three goals under this Vision for 2030, in May 2020, we drew up Mid-Term Business Plan (FY9/2020-9/2024) (hereinafter, the "Current Mid-Term Business Plan"), with the fiscal year ending September 30, 2024 as the final fiscal year. In this plan, we defined four future growth scenarios: "No.1 in Women's Healthcare", "Establish Biosimilar business", "Strengthen Overseas business" and "Evolving into sustainable Contrast Media business" to give shape to the realization of the Current Mid-Term Business Plan.

Consolidating our position as No. 1 in Women's Healthcare

A particularly important scenario among the four growth scenarios is "No.1 in Women's Healthcare".
In the fiscal year ended September 30, 2020, our sales of drugs for women's healthcare exceeded our sales of contrast media for the first time. This is partly due to fewer examinations using contrast media because of the COVID-19 pandemic. However, drugs for women's healthcare is definitely a domain which is growing each year. Compared with women in Europe and the United States, far fewer women in Japan make effective use of drugs to treat conditions such as dysmenorrhea, despite having symptoms; they do not recognize the symptoms as a disorder to begin with, and the idea of consulting a gynecology clinic to deal with the symptoms has yet to catch on. I believe that our drugs can be expected to make an even greater contribution as this situation improves.
One drug currently being developed to further contribute to the health of women around the world and achieve our goal of "No.1 in Women's Healthcare" is FSN-013. FSN-013 is a combination of the novel ingredients estrogen and progestogen currently being developed by the Belgian biotech company Mithra Pharmaceuticals (hereinafter, "Mithra"), which has formed a partnership with Fuji Pharma for its development and commercialization in Japan and ASEAN. In the EU and US, Mithra is developing FSN-013 as an oral contraceptive and has already acquired marketing approval in these and other markets. In ASEAN, OLIC (Thailand) Limited (hereinafter, "OLIC"), which is a subsidiary of Fuji Pharma, will first apply for approval of FSN-013 as an oral contraceptive, in line with its use in the EU and US markets. On the other hands, in Japan, we plan to conduct clinical trials of FSN-013 for dysmenorrhea, aiming for

release in the second half of 2024. When the provided approval is obtained, this product is expected to become one of our key products in the post-"LUNABELL® Tablets" phase.
At the same time, we are also actively engaged in awareness-raising activities, aiming to make accurate drug information available, mainly information about women's health issues, which is our area of strength. By supporting initiatives such as the "Seiri kaiteki Project" sponsored by Nikkei BP Research & Consulting and the "Marunouchi Career Juku" sponsored by Nikkei, Inc. and by encouraging a more accurate understanding of disorders specific to women, we make women be more aware of the need to make use of gynecology clinics if they feel unwell or are in pain. Moving forward, we will continue conducting awareness-raising activities whilst developing drugs to meet the needs of medical institutions and patients. Through this, we will do our best to ensure that the issues women experience at every life stage, from puberty through menopause and old age, can be resolved.

Enhancing our biosimilar pipeline with the aim of becoming No. 1 in the Japanese biosimilar market

We are also implementing a range of measures in relation to the biosimilar business aiming for the next phase growth. In November 2018, we entered into an exclusive partnership with Icelandic firm Alvotech hf. (hereinafter, "Alvotech") for the commercialization of Alvotech's biosimilar portfolio in Japan, and started development of one biosimilar medicine in Japan. Then, in November 2020, we signed an agreement with Alvotech for the development of four additional biosimilar medicines in Japan. As a result, we increased the number of products in our biosimilars development pipeline to five.
The first product in this pipeline will not be released into the market until around the end of 2023. The second is due to be released around the end of 2024 and, although development takes time, we expect to be able to continuously launch the new products through expansion of our pipeline and plan to push ahead with the development so that these products can contribute to achieving the targets under the next Mid-Term Business Plan. In the meantime, we are currently in the middle of negotiations with Alvotech for the commercialization of another three products.

Strengthening our overseas business is crucial for growth

We also plan to expand into huge overseas markets where growth can be expected. We intend to turn/develop our subsidiary OLIC, which is currently Thailand's largest CMO (pharmaceutical contract manufacturing organization), into a pharmaceutical company which manufactures and sells higher value-added own brand pharmaceuticals.
One product which will be key to this overseas expansion is FSN-013, the new drug being developed by Belgian biotech firm Mithra mentioned earlier. As explained before, we have formed a partnership with Mithra for the development of FSN-013 in Japan and ASEAN and, while we intend to obtain approval of FSN-013 for dysmenorrhea in Japan, in ASEAN countries, we plan to first file an application for approval of FSN-013 by the end of 2021 as an oral contraceptive in line with its use in the EU and US. We expect that FSN-013 will be approved in approx. 12 to 18 months and aim to start sales from fiscal 2023.
Meanwhile, North America, which has the largest pharmaceutical market in the world, is a huge market which can be expected to continue growing in the future. It is also a market where technological expertise is highly regarded. We believe that this is a market which we have to conquer in order to achieve sustainable growth. We are conducting research and development with a view to using our manufacturing technologies to supply the EU and US markets with drugs that will help solve health issues in line with our strategy under the Current Mid-Term Business Plan.

Steadily strengthening our product lineup

In Japan, we are preparing so that we can release multiple generic drugs per year in the future. A few years from now, we will be achieving multiple product launches and steadily expanding our product lineup.
Meanwhile, we applied our application for marketing approval for FSN-011-01, a new drug under development which we in-licensed from Besins Healthcare (hereinafter, "Besins"), at the end of December 2020. FSN-011-01 is a progesterone drug product used as hormone replacement therapy to balance hormones in women being treated with estrogen for menopausal disorder. There are currently no progesterone drug products indicated for hormone replacement therapy available in Japan and if FSN-011-01 is approved, it will be the first progesterone drug product approved for this indication in Japan and we believe it can make a major contribution to the treatment of menopausal disorders in Japan.

Aiming to maintain a stable supply of products through strategic capital expenditure

Within the women's healthcare domain, the market for hormone drugs, especially drugs to treat dysmenorrhea and oral contraceptives, is expanding, as awareness of women's health issues increases in society alongside the promotion of women's participation and career advancement, leading to greater recognition of conditions specific to women and stronger health awareness among women themselves. Partly to accommodate future growth in demand for hormone drugs in the women's healthcare domain, we started building a new tablet manufacturing plant at the end of 2020, aiming to triple our hormone drug (oral contraceptive) production capacity, and we plan to start manufacturing hormone drugs at this new facility in October 2022.
The Japanese market for hormone drugs, specifically drugs to treat dysmenorrhea and oral contraceptives, has yet to mature, with usage still low compared with other countries. We believe that the market is set to expand more and more alongside greater understanding of the menstrual cycle amongst the general population, and we are currently putting in place a structure to be sure of meeting future demand.
Meanwhile, work on our new vial and ampule manufacturing line was completed in April 2021. This is a line for manufacturing mainly high potency injections such as hormone drugs and anti-cancer agents and it will allow us to provide a stable supply of high potency injections and also help us to expand our product range.
We are also preparing to add a multi-syringe production line to manufacture high potent prefilled syringes in addition to the biosimilars we are planning to develop and release, and, if all goes smoothly, these lines are expected to go into operation from the end of 2023.
Furthermore, we are also increasing the ratio of R&D expenses to net sales from around 5% previously to around 10% and plan to consider drug licensing deals and business acquisitions as part of preparations to advance into the North American market.
As for shareholder returns, we plan to continue paying a stable dividend and plan to pay a dividend for the fiscal year ending September 30, 2021 of 29 yen per share (14 yen for the first half and 15 yen for the second half), which is the same amount we paid the previous fiscal year.

Strengthening corporate governance year by year

In December 2020, we welcomed two new female Outside Directors. Both of them have extensive experience in their respective areas and, also from the perspective of the diversity of the Board of Directors, we are confident that they will help improve the effectiveness of the Board of Directors. At the meetings of the Board of Directors which have already been held, they actively expressed their opinions from diverse perspectives.

Growing alongside society by providing support to women

The statement "We help people lead healthy lives by offering excellent pharmaceuticals," which is one of our corporate philosophies, encapsulates our desire to contribute to a better society by creating a positive cycle in which we constantly tackle difficult healthcare-related problems and do the things only we can do, thereby earning the trust and support of healthcare professionals, which spurs us on to make an even greater contribution.
I believe that, as a company specializing in pharmaceuticals for women, we can help address challenges facing society such as improvement in the well-being of women and promotion of the participation and career advancement of women by helping achieve a society in which women play an active role in good health, and that, through this, we can contribute to the growth of society as a whole. Whilst supporting women, we also aim to achieve sustainable growth.
Our business results for the fiscal year ended September 30, 2020 were disappointing, causing concern to our shareholders and stakeholders who put their faith in us. However, we are steadily laying the groundwork for future growth. I hope that you will continue monitoring our performance over the long term and that we can continue to reply on your support moving forward.

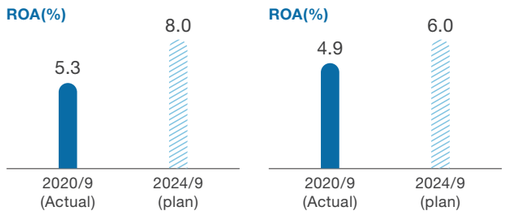
Financial Strategy

Balancing shareholders returns with a stable financial position to fund growth, towards realization of the Mid-Term Business Plan: "Fuji-rashiku wo Atarashiku (Evolving Fuji)"

Corporate Officer
General Manager of
Corporate Planning
Department
Takeshi Sato

Financial Strategy A good balance with the growth strategy

For financial targets under the Mid-Term Business Plan, we set the operating profit margin and R&D expenses ratio as benchmarks for profitability and ROE and ROA as benchmarks for financial efficiency. As a result of the purchase of treasury shares completed in February 2021, ROE of the fiscal year ended September 30, 2020 rose to 6.9%, from 5.3%. Our equity ratio of the fiscal year ended September 30, 2020 fell to 58.1%, from 64.5%. However, we still maintained a sound financial position and I believe we are well-positioned to be able to raise funds to achieve the Mid-Term Business Plan.



Research and development expenses and investments (cumulative)

Research and development expenses
18JPY Billion

Investments
32JPY Billion

* Five year cumulative total

Change in equity ratio

Before purchase of treasury shares
64.5%

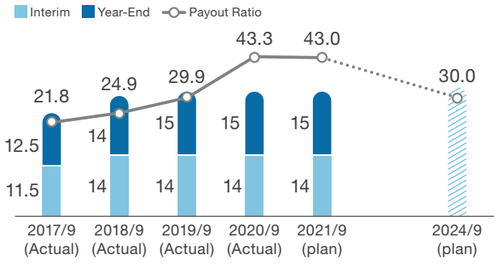
After purchase of treasury shares
58.1%

* Based on data for the fiscal year ended September 30, 2020

Shareholder Return Policy Maintaining stable dividends and increasing dividends

Our management philosophy says, “We help people lead healthy lives by offering excellent pharmaceuticals. Our corporate growth is proportional to our personal growth.” We aspire to deliver Contribution and Growth to our shareholders who support us. Contribution and Growth to shareholders means an improvement in total shareholder returns, or in other words, an increase in the share price and returns to shareholders. Increases in share price arise from the growth of our profits and improvements in the evaluation of our growth potential in the stock market. The rise in returns to shareholders is achieved through our policy on shareholder returns.
We understand that maintaining stable dividend payments to shareholders and increasing them, as a means of returning profits to shareholders, is a key management issue. We will make decisions on the distribution of profit in overall consideration of net profit, future performance trends and retained earnings for future business expansion. While making investments to provide value unique to us, we will aim to secure a payout ratio of 30% with an emphasis on stable dividend payments.
The purchase of treasury shares is another way of returning profit to shareholders, aside from dividends. In February 2021, we purchased treasury shares in conjunction with the sale of our shares by Mitsui & Co., Ltd., and we cancelled all but some of these purchased treasury shares in March 2021. We will consider future purchases of treasury shares, taking our business performance and financial position into account. However, for the foreseeable future, we intend to allocate cash flows to strategic investments required for the execution of growth strategies.

Dividends per Share (yen) & Payout Ratio (%)



IR Policy Clearly communicating our management policies and growth strategies

We will be significantly increasing the number of opportunities to provide explanations to individual and institutional investors and to speak with analysts in Japan and overseas for the purpose of clearly communicating our management policies and growth strategies to our shareholders and increasing our corporate value through dialogue.
Taking the effects of the COVID-19 pandemic into consideration, we have switched to online financial briefings since May 2020 and made videos of the briefings available on our website. We also provided our first proper briefings for individual investors on platforms such as YouTube in December 2020 and March 2021.In addition, we held a total of 25 briefings for individual institutional investors and securities analysts, an increase of 3 from the previous year. We also receive feedback and requests about briefings and other matters through the inquiry form on our website and are happy when shareholders get in touch.
Moving forward, we will continue actively increasing points of contact with shareholders and listening to all kinds of feedback to inform our management.

Vision for 2030 and Mid-Term Business Plan

We have determined Vision for 2030, which we aim to realize by the fiscal year ending September 30, 2029.
Our Mid-Term Business Plan, under which the fiscal year ending September 30, 2024 is the final year, is a concrete action plan covering the steps we need to take to realize the strategies we aim to realize during this timeframe.

Vision for 2030
~Where you want to be in 10 years~

Vision 2030 is the roadmap, that through our management philosophy, explain "What we want to achieve" and "Where we want to be" in the next 10 years from now at the end of the fiscal year ending September 30, 2029.

Contributing to well-being of women in the world

Will further deepen the management philosophy, "We help people lead healthy lives by offering excellent pharmaceuticals." While still focusing on pharmaceuticals, we plan to move beyond the boundaries to proactively contribute so that women across the world, are physically, mentally and socially fulfilled. And we are committed to make this happen.

Expanding our business to Global Market from Toyama

With our roots in Toyama, known as the cradle of medicines in Japan, we are committed to contributing to the healthy lives of people across the world, by researching and developing better drugs, and leverage our manufacturing technology to supply high quality pharmaceuticals.

Integrating the world’s happiest company and social contribution

"The world's happiest company," in which every employee of the Fuji Pharma Group feels a sense of fulfillment in their work, which leads to contributions to the society, and the appreciation from the society leads to the growth and joy of each employee, creating a virtuous circle that further contributes to the society.

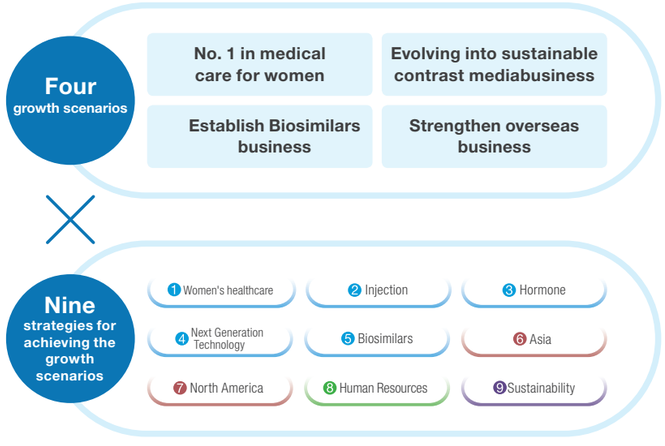
Mid-Term Business Plan
Fuji-rashiku wo Atarashiku (Evolving Fuji)

The Mid-Term Business Plan covers the first five years for getting where we want to be in 10 years as defined in Vision for 2030 and sets out specific strategies to this end.

Theme

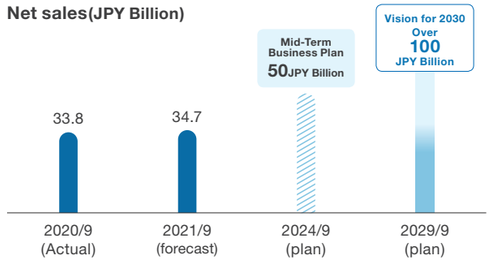
Positioning Halfway point of Vision for 2030

We broadly established four growth scenarios and set out nine strategies for achieving them.

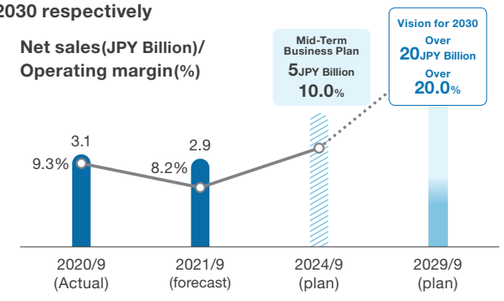


Targets under the Mid-Term Business Plan and Vision for 2030 respectively

Net sales(JPY Billion)



Net sales(JPY Billion)/ Operating margin(%)



Special Feature

Fuji Pharma's Contribution to Women

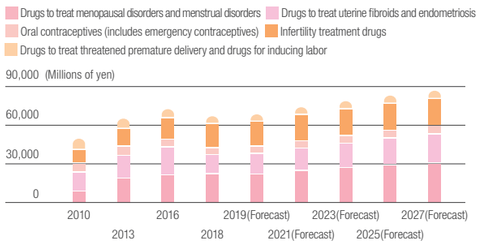
Specializing in the women's healthcare field for approx. half a century, Fuji Pharma supplies and raises awareness about the wide range of drugs to help solve the health problems women faces today.

Supporting women's health - a social challenge

Women play an active role not only in household chores and childcare but also in wider society, supporting the local community and also participating as working professionals. The active participation of women in all such aspects of society is predicated on their physical and mental wellbeing which allows them to live their life as normally. Modern-day women, who, with economic development and changes in women's lifestyles, are having fewer children, now tend to ovulate and have menstruation more often than before. In the days when women had more children, a woman may have had around 50 menstrual periods during her lifetime. This is due to long stretches without menstruation because she was repeatedly falling pregnant or breastfeeding. These days, a woman is said to experience almost 10 times as many periods as in the past. A woman's physical and mental state changed significantly due to hormonal fluctuations around the time of ovulation and menstruation each month.
Life events besides such as marriage, pregnancy and childrearing aside, hormonal fluctuation during the menstrual cycle and at each life stage i.e. puberty, reproductive period, menopause and senium, also severely undermines a woman's physical and mental health and brings about significant changes in her lifestyle and environment.
The number of patients suffering from conditions that tend to be caused by hormonal changes such as dysmenorrhea and endometriosis has also started to increase [*1]. Such conditions can not only lower a woman's quality of life but can also end up negatively affecting her work performance and reducing her future fertility.
In the Fact-Finding Survey on the Promotion of Working Women's Health[*2] conducted by the Ministry of Economy, Trade and Industry in 2018, approx, 50% of female employees answered that they had had bad experiences in the workplace due to women's health issues or similar. Studies conducted in recent years have also shown that ignorance about female hormones causes women to performance to decrease in both at the workplace and in life in general and is also hugely damaging to the economy.

For information about our awareness raising activities, see page 37 onwards.

Obstetrics and gynecology market trends by therapeutic domain*1

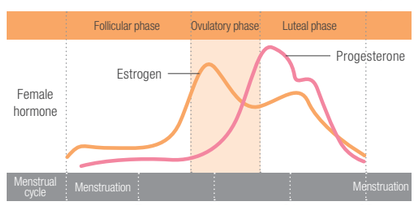


*1 2018-2019 Ethical Drugs Data Book No. 4 compiled by Fuji Keizai
*2 Initiatives for Women's Health in Health and Productivity Management published by the Ministry of Trade, Economy and Industry in March 2019

column The effects of hormones on the female body

One factor which is of huge significance when thinking about the female body is the effect of hormones.
The hormones which are particularly important for women are the two hormones produced by the ovaries: estrogen and progesterone. These two hormones are referred to as "female hormones".
Female hormones are hormones produced by the ovaries from puberty to menopause, and they fluctuate significantly during the phases of the menstrual cycle, which are generally repeated within each month. Meanwhile, women in their late 40s and 50s experience an abrupt drop in estrogen as a result of fewer ovulations. This fluctuation in female hormones has a wide range of effects on a woman's body and brain.

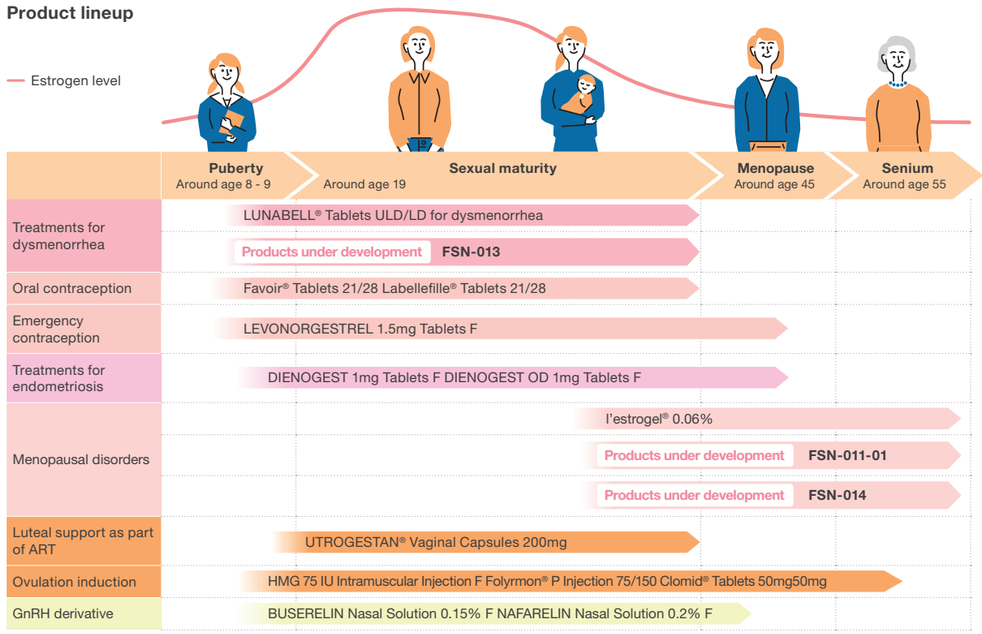
The two main female hormones and their secretion cycle



Offering a wide range of products, focusing on women's healthcare.

Hormone therapy for treating women's health issues is essential drug therapy in the obstetrics & gynecology domain. To support the health of modern-day women, Fuji Pharma offers a lineup of products to meet woman's needs at each stage of her life.

Product lineup



LUNABELL® Tablets ULD for dysmenorrhea

Favoir® Tablets for oral contraception

l'estrogel®, topical estradiol gel

UTROGESTAN® Vaginal Capsules natural progestational hormone agent

DIENOGEST OD Tablets F for treatment of endometriosis and relief of pain caused by adenomyosis

Selection of Subjects

The Portfolio Management Department takes the initiative in selecting new products that support the future of Fuji Pharma and in managing existing products. In collaboration with relevant departments, it strives to select and manage products in line with our business principles and the Vision for 2030.

Executive Corporate Officer
General Manager of the Portfolio Management Department
Atsuya Mitsuhashi

General Manager of the Business Development Department
Chaudhary Kushendra

In charge of building and managing the product portfolio

The Portfolio Management Department consists of two teams: the Portfolio Management Office and the E4 and MP Planning Office. They are responsible for optimizing and managing the product portfolio through a variety of approaches, including developing new products (new drugs, biosimilars and generics) in-house, taking over products from other companies, transferring sales of products, co-promotion and co-marketing. The department also proposes marketing strategies for new drugs and biosimilars.

It implements product life cycle management, which covers all processes related to the supply of pharmaceuticals from start to finish, including the selection of the new products best suited to our business principles and the Vision for 2030, evaluation and revision of development project priorities, and the determination of drug promotion policies to maximize the value of new drug products after its release. The Portfolio Management Department responsibly and cross-departmentally discusses and manages activities including the selection of new products, market releases and promotion after the release to pave the way for a faster, more appropriate decision-making, and is structured to facilitate the construction of an optimal product portfolio.

In charge of maximizing the value of our product pipeline

We established the E4 and MP Planning Office under the Portfolio Management Department in April 2020. It is aimed to smoothly releasing two new products in the women's healthcare domain currently under development, FSN-011-01 (MP) and FSN-013 (E4), and maximizing their value. Through this newly established team, we will seek to maximize the value of these products through close cooperation with Besins and Mithra, the companies from which we in-licensed the products, aiming to help even more patients around the world.

FSN-011-01 (MP), which filed an application for marketing approval at the end of December 2020 and which we in-licensed from Besins, is a new drug which will be our second product and the E4 and MP Planning Office is also in charge of the marketing plan for this product. Previously approved and sold in over 100 countries around the world, including the US and EU member states, this product's use is yet to be approved in Japan. FSN-011-01 (MP) is a natural progesterone drug product used for hormone replacement therapy associated with the treatment of menopausal disorder. When a development recruitment was announced by the "Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs" led by the MHLW in 2010, we applied for it and commenced development.

FSN-013 (E4), a novel safe product in-licensed from Mithra, is under development as a dysmenorrhea drug in Japan and as a contraceptive drug in ASEAN countries. The E4 and MP Planning Office plays a central role in actions for maximizing the value for this drug in Japan and the ASEAN region. FSN-013 (E4) is also being developed in other parts of the world besides the ASEAN region by other companies which have in-licensed it from Mithra. It has already been approved as an oral contraceptive in the EU and US and is expected to contribute significantly to the wellbeing of women around the world.

In line with our aim of becoming No. 1 in biosimilar business in Japan in the long term, the Portfolio Management Office is also in charge of drawing up marketing plans for new biosimilar products. Through the consideration of strategies for multiple products pipelines, which represent new therapeutic domains for Fuji Pharma, including whether to market the products ourselves or market them in partnership with other companies, the Portfolio Management Office seeks to maximize the value of the products.

Our product portfolio strategies

We are implementing product portfolio strategies targeting not only Japan but also ASEAN countries, with a focus on Women's Healthcare, Biosimilar, Injection, Hormone and New Generation Technology, which we defined as growth strategies in the Mid-Term Business Plan for realization of Vision for 2030.

Our product portfolio of the future will include not only new drug development and the development of biosimilars and generic drugs but also diagnostic drugs, medical equipment and supplies, ethical supplements and fem tech*. It will be broader in scope, unbound by the limitations of our existing businesses, to help people lead healthier lives.

* Term coined for Female and/or Feminine Technology. Products and services that use technology to address women's health issues.

Introducing products from Japanese and non-Japanese businessese

In addition to in-house development, activities to acquire rights will be important for expanding and enhancing our new product portfolio. These include acquiring from overseas companies the rights to develop and market the drugs in Japan which are under development overseas or available outside of Japan, and acquiring the rights to market the drugs being developed by other companies in Japan or co-promoting, co-marketing or taking over the authorization for manufacturing and sales of pharmaceuticals already sold by other companies in Japan.

Specific examples, besides the development of new drugs in collaboration with Besins and Mithra mentioned earlier, include involvement in the selection of biosimilars, anticancer generics and other products for development with Alvotech, a pharmaceutical manufacturer based in Iceland with which we signed an exclusive partnership for multiple biosimilars in Japan in November 2018, and with Lotus, which, as Alovotech, is an Alvogen group company and with which a capital and business alliance agreement was made in March, 2019. In collaboration with the Business Development Department which is in charge of alliances, the Portfolio Management Department also takes charge of strengthening such partnerships with overseas and Japanese companies, with a view to maintaining Fuji Pharma's sustainable growth.

New drug development pipeline in medical care for women

Japan	Indications	2020	2021	2022	2023	2024
FSN-011-01	Climacteric disorders	Application submitted in December				
FSN-013	Dysmenorrhea	Phase II completed		Phase III scheduled		
FSN-014	Climacteric disorders	Phase III in Europe and USA Phase I in Japan				

ASEAN	Planned indications	2020	2021	2022	2023	2024
FSN-013	contraception	EU/US				
		Approval obtained in US in April 2021 and in Europe in May 2021				
FSN-014	Menopausal disorders	EU/US				

* The time axis is based on our target timing.

Future prospect

Our growth strategy towards 2030, or the Vision for 2030, defines "where we want to be in 10 years" as "Contributing to well-being of women in the world," "Expanding our business to Global Market from Toyama" and "Integrating the world's happiest company and social contribution." To meet these targets by 2030, we need to boost the efficiency of product portfolio management by concentrating on management resources on priority areas. We will make greater contributions to the patients and medical practice through our products. In so doing so, we will further develop and continue to offer significant value to medical care.

TOPICS

Aiming to further contribution to women's healthcare by smoothly releasing new products and maximizing their value

MP Business Planning Team Leader, E4 and MP Planning Office, Portfolio Management Department Shigeki Kumatani

The MP Business Planning Team I belong to is a new team set up in 2020. This team is responsible for drawing the strategies for the new drug FSN-011-01, which we filed a marketing approval application in December 2020, to make sure that it will become available to more patients. Our main responsibility is to maximize the value of FSN-011-01 through life cycle management.

FSN-011-01 is a natural progesterone drug product used as hormone replacement therapy for the treatment of menopausal disorder. Currently, no progesterone drug products indicated for the treatment of menopausal disorder are available in Japan. Overseas, oral progesterone drug products are considered a very safe drug, because it is as the products made with the same chemical structure as the progesterone produced in women's bodies. No such product is available in Japan. Due to this, health care professionals have high hopes towards FSN-011-01 and we believe that it is a socially significant product which can help improve the well-being of women under menopause. I work every day to maximize the value of this socially significant drug, and to ensure that it becomes widely used to help improve women's well-being.

Research & Development Division

Grasping the wide-ranging pharmaceutical needs of medical practices to create high-quality and high value-added pharmaceutical products with excellence based on the unique characteristics of our company, the Research & Development Division executes the core functions of a pharmaceutical company.

Corporate Officer
Research & Development Division
Vice General Manager
Masayuki Naganawa

Striving to develop higher value-added products in response to requests from medical professionals

In charge of our research and development, the Research & Development Division consists of three organizations. The Planning and Development Department and the Clinical Planning & Development Department are based in the Tokyo Head Office while the Research Department is based in the Toyama Research and Development Center. They are working on the research and development of pharmaceuticals in a bid to respond to the wide-ranging needs for pharmaceuticals from those engaged in providing health care services.

Firstly, in the domain of women's healthcare, which is a priority for us, we serve the health of women in the many phases throughout their lifetimes, from childbirth and childhood, through puberty, and to menopause and senium. Aiming to help improve the well-being of women, we work to developing original drugs and generic drugs.

Looking at the status of development, the phase III clinical study of FSN-011-01 (progesterone) as a treatment for menopausal disorders with reduced side effects in hormone replacement therapy was completed and an application for marketing approval was submitted at the end of December 2020. Due to the poor oral absorption of progesterone, progestin has always been used. FSN-011-01 improves oral absorption by micronizing naturally occurring progesterone. Meanwhile, FSN-013 (estetrol & drospirenone) is a compound drug containing Estetrol, a new estrogen, currently under development as a treatment for dysmenorrhea. It is currently in Phase II testing and preparations for Phase III testing are underway. FSN-014 (estetrol), which consists only of Estetrol, completed Phase I testing as a treatment for menopausal disorders. These new drugs in the women's healthcare domain are products which we have in-licensed from Besins and Mithra respectively for further development and commercialization. Some are products which are either already being sold in other countries or are in the latter stages of clinical development, with marketing approval applied for or obtained. Throughout the development process, we liaise closely with the companies we in-licensed the products from, in order to stay abreast of the latest information on their development. The effects of the COVID-19 pandemic, which started from around the spring of 2020, have placed restrictions on our development activities that were not initially anticipated, creating a situation which temporarily prevented us from visiting medical institutions. However, we conducted development activities in cooperation with each medical institution to ensure that there were no major delays.

Moving on to biosimilars, we have already reached agreement on five agents, including treatments for autoimmune diseases and malignant neoplastic diseases, from Alvotech, and we are making progress with their development. We are also considering and discussing on another three agents in addition to these five. With the aim of becoming No. 1 in biosimilar business in Japan in the long term, Fuji Pharma has committed to expanding its product portfolio and building a business promotion and sales structure under its current Mid-Term Business Plan. In April 2020, the Biosimilar Planning and Development Section was newly established as a dedicated section for biosimilars within the Planning and Development Department. We are also strengthening our biosimilar research and development capabilities to achieve this goal.

Meanwhile in drug creation research on injections, our research on an improved dosage form for anesthesiology which was adopted by the Toyama Prefectural Government as a research subject to be subsidized in the 2019 Program for Supporting New Drug Development and Discovery was completed and development for practical application is now underway. In solid drugs, we are working on research into technology to make poorly soluble drugs soluble and miniaturization technology. We believe that such improved dosage forms and development of new drug creation technologies will make medication easier to take and help develop value-added products capable of properly responding to the needs of patients and medical professionals.

Toyama Research and Development Center (Mizuhashi, Toyama)

Conducting research and development activities for greater contributions to healthy lives

The Toyama Research and Development Center researches and develops bioactive small molecules and macromolecules and highly toxic substances. Working environments which take workers into consideration and consideration for the external environment are essential when handling such substances. The center leverages our injection prototyping facilities and solid drug prototyping facilities which fulfil such requirements to conduct drug development, with a focus on high value-added drugs. Completed in 2018, the solid drug prototyping facilities in particular are a major driving force behind our pharmaceutical development. For instance, the facilities include an organization specializing in the exploration of testing methods for active pharmaceutical ingredients and drug creation which was created in 2019. This organization established a highly sensitive world-class analytical method for the analysis of hormones in very low concentrations, the testing of which is difficult in instrumental analysis.

In recent years, we have actively introduced advanced prediction software and analysis equipment at the center to perform more in-depth structural analyses than was previously possible in an effort to improve the safety of developed drugs. We use such tools to formulate strategies to properly manage active ingredients and drugs from the development stage and to develop even better pharmaceuticals.

Future prospect

Development of FSN-011-01, FSN-013 and FSN-014 as new drugs in the women's healthcare domain and development of generic drugs and biosimilars, which widen the treatment options for patients, are picking up pace and we aim to become No. 1 in Japan in both the women's healthcare domain and the biosimilars business. We will continue to push ahead with research and development in collaboration with our partners, including Mithra, Besins, Alvotech, Lotus and other overseas companies. Furthermore, as mentioned in Vision for 2030, we will actively step into areas that we have not addressed, such as medical care for men, new generation technologies and the drug administration devices business.

In addition, we participate in the Toyama Pharmaceutical Valley Development Consortium project set up for the development of Toyama into a world-famous city of medicine as a member of the promotion committee for the development of the city of medicine and we have embarked on joint research into bio-pharmaceuticals with universities in Toyama Prefecture. The project is aimed at being a collaboration between business, government and academic institutions in the prefecture. We will press ahead in the collaborations with universities and other research institutions and with governmental offices through these activities.

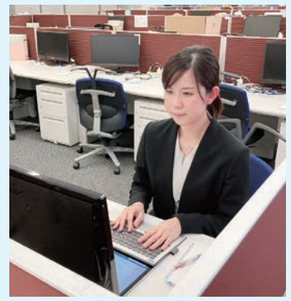
In attaining the commercialization of cutting-edge technologies and satisfying the needs of medical professionals, we will continuously collaborate with national and local governments, universities and business partners and strive to improve our research and development capabilities, as well as our drug preparation technologies.

TOPICS

Contributing to drug development through intellectual property, to make drugs available to the patients and societies that need them

Leader, Intellectual Property Section, Planning and Development Group, Planning and Development Department, Research & Development Division
Sayaka Yamamoto

Fuji Pharma develops, manufactures and sells both generic drugs and original drugs. It has both sides as a generic drug maker and as an original drug maker. Consequently, as someone in charge of intellectual property, my job in relation to generics, given that generics can only be released once the patent on the original drug expires, is to conduct research into patents. Meanwhile, my job in relation to original drugs is mainly to apply for patents on our own technologies and other rights as part of life cycle management, aiming to maximize the value of world-first or Japan-first original drugs from a patient perspective. In the Intellectual Property Section, I have the opportunity to be involved in both sides of the equation as described above, which I find very rewarding as I learn a great deal every day. I go about my work everyday, knowing that both aspects of my job will help achieve the ultimate goal of providing patients and societies with the drugs they need.



Production

We will create a truly trusted base plant through expansion of production capacity for hormones and injections and the development of a quality-focused culture unique to Fuji Pharma.

Director, Vice President
Manager of the Toyama Plant
Takayuki Kasai

Establishment of Production Technology Group Bringing together production experts to create a pharmaceutical plant that earns trust by getting the basics right

The product recalls, serious adverse events caused by contamination, non-compliance with laws and regulations and GMPs and other production-related issues that occurred at a generic drug maker at the end of 2020 have forced the pharmaceutical industry as a whole to reassess the importance and significance of production sites and plants used to produce pharmaceuticals. Toyama Plant, which is in charge of Fuji Pharma's core production operations, sees such incidents as a concern matter, and is once again encouraging workers to get the basics right, even though this is something that they have always done as a matter of course. More specifically, we are redoubling efforts to do what we have always done at Toyama Plant, namely conduct production activities which prioritize Safety, Quality, Delivery and Cost, in that order. To do this, we must create a culture of quality in which we are always scientifically thinking about the impact on quality, including action in response to deviation, process improvements, and analysis of process and quality trends. Everyone from shop floor workers and managers to executives must make consistent and steady efforts. We are making all those in positions of responsibility thoroughly implement the "3Gs" (Genchi, Genbutsu, Genjitsu), which means going to the actual place (genchi) to see the actual thing (genbutsu) with their own eyes and confirming the facts (genjitsu). Additionally, in October 2020, we established the Production Technology Group as an organization responsible for addressing concerns related to products and production processes and properly transferring technologies. The Production Technology Group has already played an active part in various areas as an expert in drug production, including the introduction of in-house developed products and in-licensed products to the plant, the transfer of technologies to other CMOs* and construction of new lines. As a department full of production expertise, it is expected to play an important role linking research and development operations and production operations.

Strengthening competitiveness to create a structure for increased production of mainstay products

To achieve our goal under the Mid-Term Business Plan of becoming No. 1 in the women's healthcare domain, we have started to increase our production capacity for hormone tablets which are defined as high potency drugs. We are steadily taking steps, with action to expand capacity at our existing fourth drug production building as a first step and drastic expansion of capacity through the construction of a new drug production building as a second step. We call this second step the Sugar Project and aim to expand drug production capacity to three times of the current level. Construction work on the new drug production building (the sixth drug production building) has started on the Toyama Plant site, aiming for completion in December 2021, and the main production equipment has also been purchased. Signifying that the building will mainly produce sugar coating tablets, the name "Sugar" is an acronym that stands for Sustainable, Sixth, Update, Growth, Auto and Reiwa. At this new building, we will initially manufacture the oral contraceptives Labellefille and Favoir, hoping to make these products available to all those who have been looking forward to an increased supply. We also intend to translate the increased capacity resulting from establishment of this new building into the production of FSN-013 (estetrol/drospirenone), a new drug in-licensed in from Mithra and currently being tested in clinical trials.
In addition, we plan to build up the contrast media business by strengthening both our own existing products and contract manufacturing services. There is still solid domestic demand for contrast media and we need to provide a stable supply commensurate with demand in the Japanese market. The plastic syringe production line at our fifth drug production building and the vial production line at OLIC are the newest lines for manufacturing contrast media for the Japanese market and we intend to operate these robust facilities at full capacity and take on production at the plants of other companies, aiming to become the leading contrast media producer in the Japanese market both in terms of production volume and the number of product lines.

Management and welfare building completed in August 2020

Building a high value-added drug supply structure and establishing GMP compliance worldwide, as foundations for the future

One of our goals under the Mid-Term Business Plan is to become No.1 in the biosimilars business in Japan. Leveraging our capital and business alliance with Icelandic firm Alvotech, we plan to research and develop many biosimilar products and market them in Japan. Since these new products will play a central role in our next mid-term business plan, we naturally intend to build a structure that will allow us to produce them in Japan and help us maintain a stable supply. Moreover, given that many of the new products we develop in-house are PFS (prefilled syringe) products, in other words, products in the same form as biosimilars, and that they are high added-value, high potency products, we plan to introduce a multi-syringe production line, that is, a production line which can be flexibly adapted for the production of both plastic and glass syringes, and cartridge injections. This new production line is expected to be completed during 2023 and will be taken into operation, starting with the production of our own original products.

In addition, a global GMP compliance project with a view to achieving Vision for 2030 was also launched from the end of 2020. As the name, the project aims to meet the GMP requirements of overseas countries but above all it aims to meet the requirements of the US Food and Drug Administration (FDA), which are considered to be the strictest requirements in the world. We have also hired a GMP consultants specialist and carefully selected members from various departments grapple every day to truly understand and apply GMPs, aiming to ensure that plants comply with the cGMPs*1. By using manufacturing facilities, such as the new SUGAR building mentioned earlier, as well as the planned hazard-response *2 multi-syringe production line, the hazard-response ampoule and vial production line, which will become fully operational in May 2021, and the hazard-response freeze-drying vial production line at the fifth drug production building, in combination with innovative manufacturing technologies created at our Research and Development Center, we will develop the U.S. market and evolve into the flagship plant needed to achieve our goal under Vision for 2030 of "Expanding our business to Global Market from Toyama."

*1 cGMP (Current Good Manufacturing Practice): Generally speaking, GMPs enforced by the FDA in the US, which is where GMPs originated, are referred to as cGMPs but since GMPs change with the times (scientific standards), GMPs based on the latest standards are referred to as current GMPs = cGMPs.
*2 Hazard-response: The containment facilities and systems for the stringent control necessary for the production of drugs with particularly high pharmacological activity, such as anticancer drugs and hormones, including the control of worker exposure and control to prevent environmental and cross-contamination

Future prospect

Overseas markets are at last within reach. To achieve our goals under Vision for 2030 and the Mid-Term Business Plan, we properly invested in facilities and equipment to keep pace with technological change, built and automated new drug production buildings and production lines, and also launched a DX project to improve efficiency and ensure data integrity. Over the past year, the COVID-19 pandemic prevented us from travelling overseas but, together with OLIC in Thailand, Toyama Plant is committed to achieving the "Evolving Fuji" vision on the drug production front through flexible multitasking across generic drugs, original drugs, biosimilars, contract manufacturing and overseas business and the development of human resources capable of demonstrating leadership.

TOPICS

Contributing to improvement of women's well-being through the realization of stable production and supply driven by production activities

Production Management Section, Production Management Group, Production Management Department, Toyama Plant
Mai Saito

The Production Management Department plays a central role in production activities spanning the acceptance of raw materials to the shipment of products. Its responsibilities include acceptance and shipment operations, raw material inventory control and cost control. We focus on routine management operations, trying to facilitate cooperation between divisions so that each plant division can devote itself to production operations in line with the three essential principles of GMP and quality guidelines.
I am in charge of solid tablets, mainly treatments for dysmenorrhea and oral contraceptives. Whilst these products are drugs, I believe that they address symptoms and concerns which women still find difficult to discuss with those around them or talk about and that more widespread use of these products will help improve women's well-being. The stable supply of drugs is our most important mission as a pharmaceutical company. Keeping this in mind, we will continue providing a stable supply of safe, high quality products through production management operations to earn even greater trust from our patients and other stakeholders.

Reliability Assurance

The teams in Toyama and in Tokyo work together to closely check the quality, safety and efficacy of pharmaceuticals supplied to markets in order to minimize the risks involved in their use.

Corporate Officer
General Manager of the Regulatory Compliance Department
Chief Pharmaceutical Officer
Satomi Sawada

In order to supply safe and secure pharmaceuticals

We have introduced strict internal quality and safety standards to ensure the safety of the pharmaceuticals we supply peace of mind to patients and medical professionals. In accordance with these standards, we monitor quality, efficacy and safety to minimize risk. We also provide data on proper use timely and appropriately to medical professionals to ensure that pharmaceuticals are properly and safely used.

To monitor safety, the Regulatory Compliance Department is cooperating the Research & Development Division, the Toyama Plant and other departments in Fuji to collect information widely from medical institutions, business partners and regulatory authorities in many countries consistently across phases from product development to the discontinuation of sales. In the fiscal year ended September 30, 2020, we acquired at least 10,000 information cases regarding safety and such accumulated information is managed by the Safety Management Group, leading to the planning and implementation of measures necessary to ensure safety and proper use. . Staff in charge will evaluate the acquired information in accordance with the procedures, and when it is necessary to report to the Ministry of Health, Labour and Welfare, revision of package inserts, transmission of proper use information, we will promptly take measures in accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Ministerial Ordinance on good vigilance practice (GVP) and other regulations. In the fiscal year ended September 30, 2020, we provided at least 30 information cases on proper use.

We also receive at least 500 cases of quality-related information each year from internal and external sources. In response to this information, we closely examine the manufacturing and quality inspection records of the product in question to investigate the causes, as well as the reference samples from the same lot and preceding and subsequent lots for detailed investigation. We then devise actions to respond to the incident, including any remedial, preventive or other measures. We also see quality information as an opportunity to improve products, using it to modify products which patients and medical professionals can then use with even greater peace of mind.

Strengthening management and alignment to make quality assurance even more reliable

To make quality assurance more reliable, we draw up an annual audit plan and carry out audits to provide guidance and exercise management and supervision. We assess risks at all plants we deal with and carry out either on-site audits or written audits depending on the risk level.

In the fiscal year ended September 30, 2020, audit activities were in some cases impacted by the ban on overseas travel and other consequences of the COVID-19 pandemic. However, we are revising our audit plan taking this and other factors into consideration and exercised appropriate management at plants. In particular, we recalled products based on the results of long-term stability testing over recent years and the verification results of the actual production situation at plants. To prevent any possible incidents in the future, we rigidly and consistently manage and supervise plants from the development stage.

Pharmaceuticals cannot be supplied to markets without authorization for pharmaceutical production and sales for each individual item. For newly developed products, the Regulatory Compliance Department is cooperating with the Research & Development Division to provide pharmaceutical affairs support and take actions towards the application and acquisition of such authorizations. In cooperation with each related plant, we work to properly carry out legal procedures for post-authorization changes in line with the regulatory requirements to maintain authorization over the long term, including applications on partially revision documentation or notify regulators of minor changes.

Steady preparation for global expansion

Within the Regulatory Compliance Department, the Quality Assurance Group, the Safety Management Group, the Pharmaceutical Regulatory Affairs Group and the Reliability Guarantee Office all are working together to strengthen the reliability assurance structure to ensure the quality, safety and efficacy of pharmaceuticals, based in Toyama and Tokyo. As we look to further expand the market for our products and strive for global business expansion, we have created a global policy on quality and safety and will continue building a groupwide reliability assurance structure to ensure the safe and secure use of our products and the peace of mind of patients and medical professionals around the world. By fully leveraging the system we introduced for global expansion to enable us to search for information about the regulations in many different countries, we will quickly study what actions are necessary to comply with pharmaceutical and other regulations in the areas we are preparing to enter. In Japan, we collaborate with overseas business partners, sharing information on matters necessary to obtain and maintain authorization in Japan and building closer ties with these companies, to support the expanding business with overseas partners in the future. Since acting globally is essential to strengthen partnerships, we will continue to provide training support to employees to improve their English language skills. Given the need to supervise safety and maintain quality when expanding our core women's healthcare products and contrast media businesses and entering new domains, we plan to strengthen cooperation with the relevant divisions and actively provide support in these areas.

Providing even greater peace of mind

Whilst there are still issues to be addressed for compliance with the Pharmaceutical and Medical Device Act, such as the digitization of package inserts, online submission of authorization applications and notifications, and further strengthening of the legal compliance structure, we will ensure actions are completed by the specified deadline, actively participating in activities of industry associations to collect and share information with the regulatory authorities and within the industry and seeking cooperation with relevant departments within the company. We will also strengthen structures for checking that drugs are manufactured and marketed appropriately in accordance with approvals and, as part of our efforts to maintain a stable supply of pharmaceuticals, we will continuously conduct inspections to gain an understanding of the actual status of production and quality control, and manage plants more closely.

In initiatives to improve operations, we are pushing ahead with efforts to increase outsourcing and introduce new systems. In operations related to compliance with Ministerial Ordinances on GVP and good quality practices (GQP), systems enabling pharmaceutical sales representatives to report hazard incidents and quality information and systems that enable the communication of safety information went into full operation in October 2020, realizing the simplification of business collaboration and visualization of work progress management. For more efficient management of GQP operations, we plan to promote the introduction of systems for managing quality information, progress of action on process issues and improvements, training provided and completed, and other quality-related data without omission, and we will work closely with plants to improve product quality.

Cooperation with relevant departments both inside and outside the company is essential for reliability assurance operations and united efforts to maintain and improve quality, safety and efficacy are required. By stepping up the development of human resources and strengthening our organizational adaptability, we will provide pharmaceuticals that patients and medical professionals can use safely and with peace of mind.

TOPICS

Smoothly implementing the cycle necessary for the correct use of pharmaceuticals

Drug Safety Management First Section, Safety Management Group, Regulatory Compliance Department
Yuki Shiroyama

I am involved in operations related to the collection and evaluation of drug safety information and to take action accordingly within the Regulatory Compliance Department. I collect and evaluate safety information from a wide range of sources including medical institutions, medical literature and associations, regulatory authorities across the world, and partners in Japan and overseas, and then take steps such as revising PMDA reports and package inserts and providing information on correct use to medical professionals in a timely and appropriate manner. A cycle of events is required for the correct use of pharmaceuticals: the optimal drug and drug form meeting the patient's symptoms and the appropriate dosage and administration are determined based on accurate diagnosis by the doctor; the drug dispensed accordingly is then used correctly by the patient after sufficient explanation to ensure his or her understanding; the effects and any adverse reactions are evaluated and reflected in subsequent prescriptions. I work every day knowing I am responsible for providing reliable drug information so that patients and medical professionals can use our pharmaceuticals more safely and with greater peace of mind and to smoothly implementing this correct use cycle.

Sales

The Sales Division is composed of the Strategic Marketing Planning Department in charge of planning sales activities and the Sales Department. It provides information on the pharmaceuticals we deal in chiefly to medical professionals in obstetrics, gynecology and radiology.
Each one of us endeavors to acquire accurate knowledge about products and diseases to respond to the needs of medical professionals.

Corporate Officer
General Manager of the Sales Division
Syuhei Morita

Focusing resources in priority areas

To efficiently provide high quality information, we select priority products each fiscal year and focus our sales resources on them. For the fiscal year ended September 30, 2020 (the 56th term), we defined twelve priority products. Each priority product is a distinctive group of products. Together they account for a majority, which is, more than 50% of our total sales. The Strategic Marketing Planning Department, in charge of planning sales activities, drew up sales strategies for the individual priority products. The Sales Department implemented these strategies by developing them on the medical frontlines to efficiently provide high quality information and to stretch sales figures. Despite the effects of the COVID-19 pandemic such as reluctance to seek medical care and treatment and testing delays, our sales of priority products in the gynecology domain rose 3.9% year on year, supporting our business performance.
As an achievement of our sales strategies, our presence improved in the domains of acute medical care and women's healthcare, under which most of the priority products are under. We understand that we made a good start towards achieving the growth scenarios under the current Mid-Term Business Plan of "Becoming No.1 in Women's Healthcare" and "Evolving into sustainable Contrast Media business". For a long time, diagnostic drugs accounted for the largest share in our total sales, but in the fiscal year ended September 30, 2020, hormone drugs took the top spot. Whilst this is largely attributable to the absence of branded contrast media in the diagnostic drugs category, Fuji Pharma's stronger positioning in the women's healthcare domain was also a contributing factor.
Starting from the fiscal year end September 30, 2021, we are also preparing to "Establish Biosimilar business", which is another growth scenario under the current Mid-Term Business Plan mentioned above, in addition to the activities conducted thus far.

Activities in each medical fields

Fuji Pharma is a pharmaceutical company with strength in manufacturing and selling pharmaceuticals, mainly in the fields of acute medical care and women's healthcare. The following discusses our activities in each of these two domains.
To improve the quality of our activities in the acute medical care domain, we appointed pharmaceutical sales representatives primarily in charge of advanced acute medical care to hospitals across the country in the fiscal year ended September 30, 2017, and studied the best way to provide information to large hospitals which have changed significantly over the past few years, striving to improve detailing skills and knowledge levels. Especially in the radiology field, we are the largest supplier of iodine in the domestic market, holding a market share of approx. 75% or more, receiving overwhelming support in the generic drug market. From this point in the industry, we engaged in activities at academic conferences and provied precise information to ensure safe contrast radiography examinations - activities which, I believe, were very much appreciated.
In the women's healthcare domain, we provided a wide range of products to help protect sexual and reproductive health and rights*, including oral contraceptives and emergency contraceptives and UTROGESTAN® vaginal capsules and Clomid® in the assisted reproductive technology (ART) domain, and we used a combination of tools to provide information to many medical professionals. Meanwhile, we are working hard to educate employees about peripheral information related to women's health in an effort to improve the abilities of our pharmaceutical sales representatives. We also provide accurate health care information to the public through the LiLuLa health support app for women and work to identify presymptomatic diseases. We understand that our extensive activities have increased our presence in obstetrics and gynecology. We believe that, as a result of our activities, we succeeded in making a much greater contribution to protecting sexual and reproductive health and rights.

* Refers to freedom and legal rights in relation to sex and reproduction; including the right to self-select freely whether or not to have children.

Clomid® Tablets for induction of ovulation

UTROGESTAN® Vaginal Capsules natural progestational hormone agent

Future prospect

With soaring social security and medical expenses rising due to aging, the environment pharmaceutical businesses are experiencing are becoming more severe. The decision to introduce annual NHI price revisions from 2021 has been made. The scope of products covered in the revisions made in April 2021 was far greater than the industry had anticipated, and the industry must prepare for an even severe operating environment in the future. Meanwhile, the restrictions on visits to medical institutions are becoming even stricter due to the effects of the COVID-19 pandemic. With some theory has been talked about that pharmaceutical sales representatives are no longer necessary, we need to flexibly adapt to the situation to remind people the value of our pharmaceutical sales representatives, sensitively perceiving the needs of the medical frontline in light of changes in laws, regulations and systems relating to pharmaceuticals and promoting to acquire superior knowledge on diseases and products and remote meetings to efficiently conduct sales activities, in order to achieve the current Mid-Term Business Plan. Regarding remote meetings in particular, we made effective use of web conferencing as part of our information provision activities during the fiscal year ended September 30, 2020, and are successfully exploring new ways of providing information. In November 2020, Fuji Pharma signed an agreement for joint development and distribution of FSN-013, a drug currently under development, with M3, Inc., which offers a specialized web portal for medical professionals and marketing support services to pharmaceutical companies. Through initiatives with M3, Inc., we will promote to integrate DX initiatives into our information provision activities, as stated in the current Mid-Term Business Plan.
To achieve our Vision for 2030 and our current Mid-Term Business Plan and to make a greater contribution to more patients in the future, it is necessary to make full use of our abundant experience we gained in selling pharmaceuticals in different categories such as generics, biosimilars, and new drugs. We will need to continue implementing the existing initiatives to improve productivity and efficiency including strengthening initiatives with wholesalers and other business partners, using digital technologies, in order to speed up implementation of the PDCA cycle in each division to achieve sales plans, and strengthening internal training to ensure information provision activities in compliance with laws and regulations. In addition, we will need to introduce comprehensive initiatives to deal with the COVID-19 pandemic - an unprecedented situation in which past experience will not work. With this, a comprehensive effort will be aiming to an industry leading organization, which is capable of responding to any circumstances it may face.

TOPICS

Taking pride as a specialty pharmaceutical company, carrying out information provision activities.

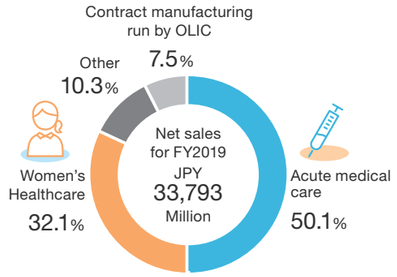
Kansai Second Sales office, Kansai Branch, Sales Department, Sales Division Maya Hirose

Pharmaceutical sales representatives are responsible to disseminate the proper use of our pharmaceuticals to patients by providing, collecting and transmitting information. When I go about my duties as a pharmaceutical sales representative, I am always aware of this responsibility and try to bridge the gap between patients and pharmaceuticals. I provide information and propose pharmaceuticals to meet the patient's needs and the approaches of medical professionals, always striving to raise awareness about products and diseases. As well as providing information about our pharmaceuticals, I endeavor to raise awareness about diseases in the hope that this will encourage the patient's treatment. Especially in my activities in the women's healthcare domain, I aim to make treatment more readily available to patients and increase their understanding about diseases, by introducing them to LiLuLa and distributing booklets to medical institutions to raise awareness about specific diseases. These days, patients have a range of options and Fuji Pharma's products are one of these options. I do my work every day hoping that I am in some way, are helping many patients.

Principal Sales Data

We are a pharmaceutical company focusing on the women's healthcare domain and the acute medical care domain.
For the fiscal year ended September 30, 2020, net sales in acute medical care stood at 16,926 million yen, accounting for 50.1% of total net sales, those in women's healthcare at 10,836 million yen, accounting for 32.1%, and those in contract manufacturing run by OLIC at 2,532 million yen, accounting for 7.5%. The termination of a license agreement for contrast media and generic competition for LUNABELL®, among other factors, caused net sales to fall by 2,486 million yen, or 6.9%, from the previous fiscal year. However, this result was almost in line with the initial forecast.

Sales share by medical field

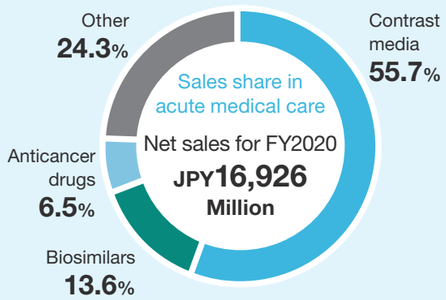


Net sales by medical field

Medical field (JPY Million)	FY2016	FY2017	FY2018	FY2019	FY2020	YoY Change Value	YoY Change %
Acute medical care	19,997	20,264	21,895	19,340	**16,926**	-2,414	-12.5%
Women's Healthcare	9,582	10,212	10,802	10,756	**10,836**	80	0.7%
Other	2,413	2,509	2,734	3,643	**3,497**	-146	-4.0%
Contract manufacturing run by OLIC	2,236	2,400	2,476	2,539	**2,532**	-7	-0.3%
Total	34,229	35,387	37,909	36,279	**33,793**	-2,486	-6.9%

* Amount for contract manufacturing run by OLIC is amount after consolidation adjustments.

Acute medicalcare

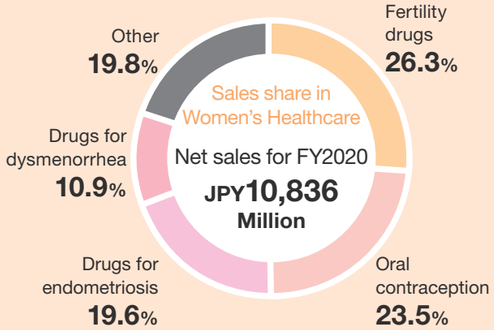


Contrast media sales amounted to 9,423 million yen, 55.7% of sales in the field of acute medical care. We signed a sales license agreement with a European firm for its contrast medium in 2014 and had sold it since then. The contract came to an end and sales of this product were transferred to this European company's subsidiary in Japan on January 1, 2019. That became a main reason for the 2,414 million yen year-on-year slide in net sales.


Contrast media


Biosimilars

Women's Healthcare



In women's healthcare, sales of LUNABELL® tablets for dysmenorrhea continued the downward trend seen last year due to generic competition. However, thanks to the contributions of other products such as Dienogest Tablets, released in the fiscal year ended September 30, 2017 for treating endometriosis and improving adenomyosis-associated pain, and oral contraceptives Favoir® Tablets and Labellefille® Tablets, overall sales increased by 80 million yen year on year.

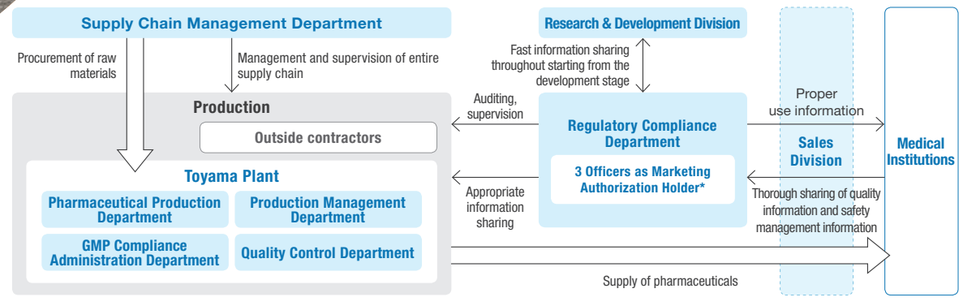

Fertility drugs


Drugs for endometriosis

Special Feature

Structure Supporting Production Management, Quality Control and Stable Supply

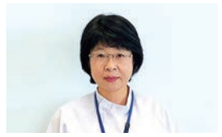
We have built a structure for supplying pharmaceuticals which patients and medical professionals can use safely and with peace of mind.
The Regulatory Compliance Department, which is in charge of important business processes for managing the safety of pharmaceuticals, including good vigilance practice (GVP), reports directly to the President and audits and supervises production activities both inside and outside the company. The Chief Pharmaceutical Officer, who is also a Corporate Officer and General Manager of the Regulatory Compliance Department, provides reports, opinions and other information related to pharmaceutical safety management at Corporate Officer Meetings and other meetings in a timely and in an appropriate manner. We also provide employees with training on a regular basis to instill a culture of compliance and ensure every employee performs his or her duties with a high level of awareness.
Meanwhile, the Supply Chain Management Department is in charge of managing the entire supply chain and ensuring a stable supply.



Further information on compliance can be found here ⟹ P. 31

* 3 Officers as Marketing Authorization Holder denotes the Chief Pharmaceutical Officer, Quality Assurance Manager and Safety Control Manager who must be appointed to ensure the quality of products ensuring patients safety.

Message from the Officer in Charge



Corporate Officer
General Manager of the Regulatory Compliance Department
Chief Pharmaceutical Officer
Satomi Sawada

Pharmaceuticals supplied to the market must be produced by a manufacturer (at its own plants or those of outside contractors) under an appropriate management structure, and assurances both in terms of production and quality must be obtained. This includes appropriate management not only of the pharmaceuticals that are produced but also of the raw materials and materials that are used to produce them. We endeavor to gain an understanding of whether manufacturers of such raw materials and materials exercise appropriate management through detailed information sharing and cooperation and we implement a cycle of carrying out inspections and making improvements where necessary. However, in recent years, we have had to recall products because they were shipped without sufficient evaluation of production and quality and we have been party to events that prevent us from properly fulfilling our responsibility as a pharmaceutical manufacturer, that is, maintaining a stable supply and ensuring safety and efficacy for patients.
I believe that raising awareness, in other words, sharing issues with manufacturers and working together to solve them, and properly verifying that issues are resolved are the key to maintaining a stable supply.
Cooperation between safety control and quality assurance departments also plays an important part in quickly discovering signs of problems with the quality or safety of pharmaceuticals and minimizing the impact on patients and medical professionals.
When we adopt a pharmaceutical life cycle perspective, then initiatives to ensure quality, safety and efficacy start from the development stages. Through cooperation with relevant departments both inside and outside the company, I will see to it that pharmaceuticals with marketing approval are manufactured at plants in accordance with the approved specifications and that the expected quality, efficacy and safety are ensured and a stable supply is maintained.

Director,
Executive Corporate Officer
General Manager of the Supply Chain Management Department
Toyoyuki Kamide

The Supply Chain Management Department used to be the procurement department for Toyama Plant and was mainly in charge of procuring raw materials, managing deliveries of items manufactured under contract and developing new manufacturing contracts. However, from the fiscal year ending September 30, 2021, it has a created a Stable Supply Management Section for coordinating the stable supply of products, and has been restructured into an organization that reports directly to the president and manages and supervises our entire supply chain in addition to its previous duties.
In the past, product recalls, raw material procurement issues and other events have unfortunately prevented us from maintaining a stable supply of products. For a pharmaceutical company, maintaining a stable supply of pharmaceuticals is an important responsibility and we recognize that creating a structure that allows medical professionals and patients to use our products with confidence is an urgent issue that must be addressed. We have therefore set up the Stable Supply Committee led by the Supply Chain Management Department and attended by those in charge of supply from each department, to promote information sharing and also discuss solutions to issues over the medium and long term. There are many issues to address but we will solve these one by one and work together to build an unshakable stable supply structure.

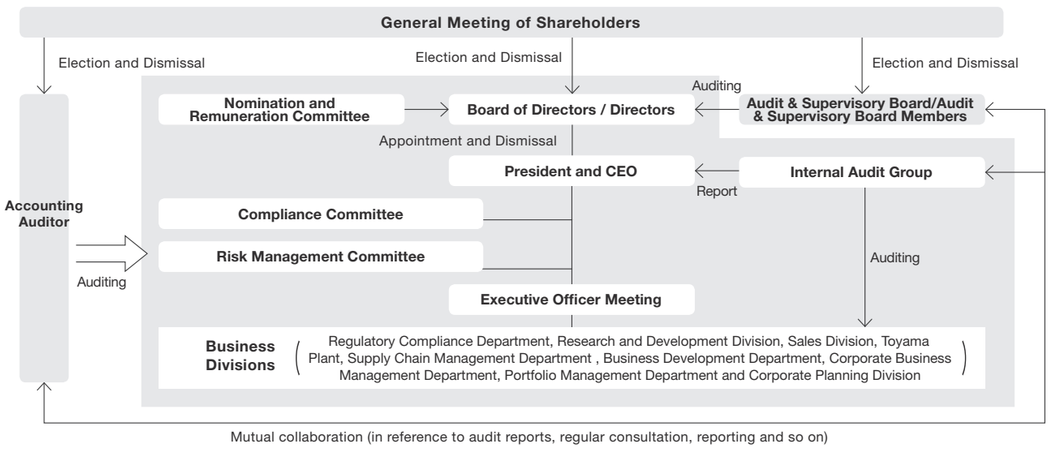
Corporate Governance

Basic Perspective

Fuji Pharma has the business principles: “We help people lead healthy lives by offering excellent pharmaceuticals.” and “Our corporate growth is proportional to our personal growth.”
In accordance, we will continue to develop, manufacture and sell high-quality pharmaceuticals to meet our responsibilities to shareholders, employees, medical professionals and other stakeholders. We will make swift and flexible decisions with transparency and independence to achieve continuous growth and medium- and long-term improvement in corporate value.

Corporate Governance Structure

As a company with an audit & supervisory board, we have built an appropriate audit structure through cooperation between the Audit & Supervisory Board, the Internal Audit Group, and the Accounting Auditor. We adopted the current structure, believing that it would allow us to ensure the objectivity and neutrality of the supervisory function.



Board of Directors	The Board of Directors is composed of a total of ten Directors (of whom, six are Outside Directors) and it assesses and determines matters stipulated in management policies and laws and regulations as well as other important matters related to business execution as appropriate and also supervises business execution. We also made the term of office for Directors one year, to swiftly adapt to changes in the management environment and further clarify the responsibility of Directors. In addition, we have adopted a structure under which meetings of the Board of Directors are attended by all Audit & Supervisory Board Members, allowing them to audit business execution by Directors.
Executive Officer Meeting	We adopted the executive officer system to accelerate information sharing for business execution and initiatives to address management issues and an Executive Officer Meeting is convened twice a month, in principle. As an advisory body to the President, the Executive Officer Meeting is composed of the President and Corporate Officers from each department and it assesses business execution in each department and the status of execution is reported to the Board of Directors as necessary.
Nomination and Remuneration Committee	We established a Nomination and Remuneration Committee as an advisory body to the Board of Directors to ensure the transparency and fairness of the decision-making processes for the nomination of Directors and the determination of remuneration. This committee is composed of three Directors in total, two of which are Outside Directors and one of which is an Inside Director. The Board of Directors seeks advice from this committee before making decisions on the election or dismissal of Directors and Corporate Officers, matters concerning remuneration for, or the election or dismissal of the President and Chief Executive Officer (CEO) and policies regarding the remuneration system and remuneration levels.
Audit structure	The Audit & Supervisory Board is composed of a total of three members (two of which are Outside Audit & Supervisory Board Members). Each Audit & Supervisory Board Member carries out audits of business execution by Directors by attending meetings of the Board of Directors and inspecting the overall business and financial situation in collaboration with the Accounting Auditor and the Internal Audit Group, in accordance with the audit policies, division of duties and other procedures established by the Audit & Supervisory Board.
Accounting Auditor	KPMG AZSA LLC is responsible for our accounting audits.

Initiatives to improve the effectiveness of the Board of Directors

We implement a range of measures to ensure that Directors and Audit & Supervisory Board Members properly fulfil their roles and responsibilities as expected.
Firstly, when Outside Directors and Outside Audit & Supervisory Board Members take up office, we provide them with various training opportunities (such as briefings for newly appointed officers and training for Outside Officers), including providing them with necessary information such as our company profile, management policies and management plans and trends in the pharmaceutical industry. We also offer Directors and Audit & Supervisory Board Members the opportunity to take part in seminars and training delivered by attorneys-at-law, certified public accountants and other experts at our expense, when necessary.
In addition, we conduct an annual survey to all the Directors and Audit & Supervisory Board Members for analysis and self-evaluation to ensure and improve the effectiveness of the Board of Directors. The survey is distributed to each Director and Audit & Supervisory Board Member in October, at the beginning of fiscal year. The results and response measures are reported to the Board of Directors meeting in November, although this reporting may depend on the details of the measures. In the self-evaluation conducted in 2020, management issues raised included development of the next management team, business execution under the protracted COVID-19 pandemic, product strategies, diversity and the SDGs. On the occasion of the survey distribution in the following October, the status of implementation of the measures in the 12 previous months is reported.
While the self-evaluation is estimated to ensure the effectiveness of the Board of Directors, we will strive to make sure that the Board will spend more time discussing significant managerial issues and projects and information sharing in preparation for the discussion will be enhanced to further increase its effectiveness.

Subject	All the Directors and Audit & Supervisory Board Members
Method	Questionnaire
Assessment	Fundamental five-grade rating with free comments
Implementation	Assessing the full-year status for the previous fiscal year at the beginning of each new fiscal year
Principal survey items	Operation of the Board of Directors Supervision of development of prospective management team members Appropriateness of the standards in reference to the Board of Directors (in terms of the number of matters subject to resolution and reporting) Appropriateness of information offered to Outside Officers

Message from Outside Director

Seeking to enhance Fuji Pharma's corporate value in the medium and long term by strengthening governance whilst valuing its corporate philosophy

Outside Director Tadahiro Kozawa

The unpredictable COVID-19 pandemic continues to stoke uncertainty for Japan's economy and the world economy. Reforms in the health care and pharmaceutical industries are also likely to be accelerated by factors such as the disruption to health care caused by COVID-19 and the NHI drug price revisions of recent years. In response to this environment, we have implemented growth strategies to attract, retain and develop human resources alongside business growth strategies including researching, developing and marketing original drugs in Japan, marketing pharmaceuticals overseas, forming business alliances with overseas companies, and improving productivity at plants in Japan and overseas.
I have served as an Outside Director at Fuji Pharma for many years and, based on my awareness of the aspirations embodied in its corporate philosophy, I have cooperated with and supported Corporate officers to ensure that judgments that will help boost Fuji Pharma's corporate value are made in relation to resolutions and reports at meetings of the Board of Directors.
In addition to challenges such as pursuing development, forming alliances with other companies and improving production management and quality control, we have been implemented working from home in response to government calls to avoid commuting and curb the spread of the virus within the company during the pandemic. I believe that, under these circumstances, managing the everyday business activities and the health of individual employees smoothly and appropriately, taking action to strengthen business collaboration across the entire organization in accordance with policies, and to increase work motivation across the Group are pressing governance-related issues.
When addressing these many issues, it is important to clarify priorities and share these with all relevant parties. Moreover, I believe that timely information sharing through "visualization" of the business processes of each department is also important for business execution.
In my view, when every employee within an organization is strongly aware of his or her responsibility towards a broad range of stakeholders, including customers, business partners, other employees, shareholders and society, and performs his or her everyday duties sincerely and diligently, meets confidence and expectation of customers and society, and continues to produce added value, this will ultimately lead to enhancement of corporate value.
In my role as Outside Director, I will also work to increase corporate value, seeking communication with Corporate Officers whilst maintaining an appropriate tension and distance and strengthening governance whilst building a relationship of trust.

Risk management

We have formulated the Companywide Risk Management Regulations for the purpose of identifying, analyzing and evaluating in advance any event that may negatively impact our business activities and taking appropriate action against it to meet the objective of internal control. In accordance with these regulations, the Risk Management Committee, composed mainly of heads of divisions and managers, performs risk assessments to develop a companywide risk management system and to identify risk management issues. Risk assessments are conducted based on the objective evaluation items. To address any event that the assessment finds to have a high level of risk, a risk response plan is formulated, and related organizations are to take action in accordance with the plan. This committee's activities are reported on a regular basis to the Board of Directors and to the Executive Officer Meeting.

Managerial Crisis Management

We have prepared the "Crisis Response Procedures Sheet" provided for in the Managerial Crisis Management Regulations, clearly setting out in advance guidelines for responding to any such crisis. We use this Crisis Response Procedures Sheet to formulate disaster drills, the standards for establishment of a task force, the initial response and other procedures to be followed in the event of various managerial crisis scenarios such as the sudden outbreak of an infectious disease like COVID-19 pandemic, an earthquake in a given region of Japan, or other wide-area disaster or conceivable incident, and we ensure that all officers and employees are familiar with these procedures. We have also introduced to a "safety confirmation system" as a means of ensuring that employees and the company can make contact with each other in the event of disaster and established procedures for quickly verifying whether employees are safe.
Meanwhile, for Toyama Plant and Toyama Research and Development Center, we created a "Flood Response Manual" setting out measures to be taken in normal times and guidelines for responding to a flood, for the purpose of estimating in advance the enormous disruption to business execution that would be caused by a flood and ensuring the safety of employees and minimizing the damage in such an event.

Response to COVID-19 pandemic

To respond to the COVID-19 pandemic, we established an information liaison committee consisting of the President and CEO and those responsible for individual organizations. It gathers necessary information about changes in the situations surrounding the pandemic and the measures taken by different national and local governments. We have thus constructed a system to ensure we are capable of taking timely and appropriate action to respond to events inside and outside the company. Primarily guided by this committee, we have quickly determined and announced our action policy to prevent infection among those visiting medical institutions, those working at them, our business partners, employees, their family members and all other stakeholders and to ensure the stable supply of the pharmaceuticals we manufacture, without disruption.
We will keep a close eye on the circumstances surrounding the COVID-19 pandemic and continue to take action to fulfill our mission of stably supplying high quality pharmaceutical products.

Compliance

Our business of manufacturing and selling pharmaceuticals is directly linked to the lives of people. We are therefore aware that we must always act with a high sense of ethics. Based on this idea, for the purpose of raising awareness for compliance and thorough compliance infiltration among all officers and employees, we have established a Code of Conduct on Compliance, Standards of Conduct on Compliance and Compliance Management Regulations under the initiative of the Compliance Committee.
The goal of the Compliance Committee, composed of the heads of divisions and managers, is to plan, implement and improve compliance structures and instil corporate ethics and compliance in employees. In 2020, we launched the Compliance Newsletter. It has since been regularly published and viewed by all employees. We also provide separate departments with opportunities to learn about compliance using the newsletter and carry out a range of other measures to further raise compliance awareness among individual staff members. We require that all employees receive e-learning compliance training at least once a year in an effort to make sure that they conduct corporate activities while always considering compliance. The Committee's activities are regularly reported to the Board of Directors and to the Executive Officer Meeting.
We have also established internal and external contact points for whistleblowers so that they have options available to consult and notify us of any internal conduct actually or possibly constituting a compliance violation. Under the system, all employees can use the contact points to seek advice or make a consultation / report on violations of laws and regulations, fraud or unethical behavior committed at an organizational or individual level in the course of business activities or at a workplace. The Compliance Committee reviews the effectiveness of the whistleblowing system and makes improvements in an effort to improve the system's effectiveness.

Initiatives to improve the effectiveness of the Board of Directors

Item	Outline	Response
1. Statutory Regulations	• Possibility of recall of regulated products in case of revocation of licenses or approvals due to violation of laws • Possibility that amendments to laws and regulations will impact the Group's financial position and its business results	• Compliance with Pharmaceutical and Medical Device Act and associated laws and regulations as well as various terms and conditions necessary to acquire the licenses and approvals
2. Pharmaceutical Product R&D	• Possibility that problems with our own clinical development or issues faced by collaborative research or business alliance partners or contractors prevent R&D activities from proceeding as planned, causing costs to rise or leading to development being delayed, suspended or abandoned	• Minimization of risk damage through the incorporation of solutions to issues in contracts with external partners
3. Industry Competition	• Significant decline in market prices due to competition from numerous rival manufacturers • Decline in our sales due to strategies by original drug manufacturers in Japan to preserve market share	• Implementation of cross-departmental measures to ensure accumulation of sales, such as reducing costs by lowering raw material procurement costs and reviewing production methods
4. Raw Material Procurement	• Possibility that product prices rise due to soaring prices of raw materials or that it is difficult to obtain raw materials over an extended period of time due to fluctuation in the raw material demand-supply balance, domestic or international restrictions on raw materials or quality concerns originating from the makers of such raw materials	• Establishment of Stable Supply Committee to regularly check the procurement status of raw materials and to promptly take groupwide measures when risks arise • Gradual development of multiple supply chains for important products
5. Adverse Drug Reactions and Product Quality	• Recall of products or other impacts due to unexpected adverse drug reactions after a product goes to market, the presence of impurities in products, quality changes associated with changes in raw materials or production methods or changes in restrictions imposed by regulatory authorities	• Introduction of "Quality Management Review" for quality control • Supervision and confirmation of the possibility of foreseeable quality problems arising by a dedicated section within the Regulatory Compliance Department
6. Delayed or Suspended Product Supply	• Possibility of disruption in the supply of products due to the suspension of operations at production facilities owing to technical or regulatory issues or natural disasters	• Establishment of Risk Management Committee and formulation of alternative supply plans and supply recovery procedures in the event of disaster
7. Reliance on Specific Product	• Possibility that sales of Iopamidol (formerly called Oypalomin), which accounted for approximately 20% of net sales in the fiscal year ended September 30, 2020, stopped or decreased significantly, impacting the Group's business results	• Having the Supply Chain Management Department report directly to the President to strengthen supply chain management • Introduction of "Quality Management Review" for quality control • Reduction of reliance on a specific product by launching new products to expand the portfolio
8. Revisions to National Health Insurance Drug Price List	• Possibility of lower drug prices due to annual NHI drug price revisions from 2021	• Sale at reasonable prices taking profitability into consideration • Continuous cost reductions
9. Litigation	• Possibility that makers of original drugs initiate legal action for infringement of process patents or other intellectual property rights on the approval of generics • Possibility of being taken to court over such issues as product liability, harm to the environment, and labor issues after product goes to market	• Checking of litigation risks by intellectual property department in relation to patents and legal department in relation to laws and regulations to lower the possibility of risks materializing
10. Offset (Elimination) of Carrying Amount of the Parent's Investment in Each Subsidiary and the Parent's Portion of Equity of Each Subsidiary (Goodwill)	• Possibility that impairment of goodwill is recognized when the profitability of OLIC declines due to a significant change in the operating environment or business, impacting the Group's business results and financial position	• Efforts to maintain and improve the profitability of OLIC including putting the Corporate Planning Department in charge of affiliated companies and creating opportunities for discussion based on regular reports
11. COVID-19 Pandemic	• Possibility that cases of COVID-19 are found among Group employees, affecting research and production activities	• Formulation and implementation of Company policy for dealing with COVID-19 as disclosed from February 2020
12. Risks Related to IT Security and Information Management	• Possibility of disruption to business caused by system failure, computer viruses, cyber attacks and other security threats • Possibility of damages, administrative disposition and loss of public trust as a result of the leakage of personal information or other sensitive data	• Delivery of regular information security training for all employees of the Company
13. Risks Relating to Attracting and Retaining Human Resources	• Possibility that difficulties in attracting and retaining human resources and problems with the development of human resources will affect the Company's business results and financial position	• Focus on attracting, retaining and developing human resources in line with a corporate culture which has always attached importance to human resources
14. Risks Related to Digitalization	• Possibility of being slow to respond to digitalization, incurring more costs than competitors and lagging behind with information security measures	• Launch of specific initiatives in three areas Sales Division, Toyama Plant/Toyama Research and Development Center, and Head Office corporate functions, in line with goal of digitalization under the current Mid-Term Business Plan
15. Risks Related to Upfront Payments for Exclusive Distribution Rights	• Possibility of recognition of an impairment loss when impairment is judged to have arisen on upfront payments for exclusive distribution rights under contracts recorded under "long-term advance payments"	• Implementation of appropriate evaluation by an outside specialist, where necessary, on the recording of long-term advance payments • Continued evaluation in an appropriate manner every period thereafter • Implementation of evaluation and verification of development progress and distribution plans, including putting the Business Development Department in charge of such business creating opportunities for discussion based on regular reports
16. Risks Related to Investment in Partners	• Possibility of recording a loss on the valuation of investment securities due to a fall in the reference price in the case of listed shares or due to impairment of the corporate value assumed at the time of acquisition resulting from changes in the business environment or other factors in the case of unlisted shares	• Implementation of appropriate evaluation by an outside specialist where necessary on the recording of unlisted shares • Continued evaluation in an appropriate manner every period thereafter • Efforts to help the share issuer maintain and improve profitability, including putting the Corporate Planning Department in charge of such business and creating opportunities for discussion based on regular reports

* Forward-looking statements contained in this report reflect the Group's judgment as of December 18, 2020. For more details on these risks, please refer to the annual securities report.
https://www.fujipharma.jp/__upload/S100KDTI.pdf

Officers (as of May 31, 2021)

Directors

Chairman and Representative Director

Hirofumi Imai

Joined Fuji Pharma in 1987. After serving as president and representative director, he was appointed as chairman and representative director in April 2016.

President & CEO
General Manager of the Research and Development Division

Takayuki Iwai

Joined Mitsui & Co., Ltd. in 1986. Assigned on loan to Fuji Pharma in 2006. After serving as Senior Vice President of Mitsui & Co. (USA), Inc. and General Manager of the Americans Business Unit of theConsumer Service Business Goods Division, joined Fuji Pharma in 2019. Appointed as President and CEO in December 2019.

Director, Vice President
Manager of the Toyama Plant

Takayuki Kasai

Joined Shionogi & Co., Ltd. in 1985. After serving as Manager of the CMC Office and the Investigational Drug Production Department in the Production Research Laboratory of Shionogi & Co., Ltd. and as Chairman of the Board and President of Bushu Pharmaceuticals Co., Ltd., joined Fuji Pharma in 2016. Appointed as Director and Vice President in December 2016

Director,Executive Corporate Officer
General Manager of the Supply Chain Management Department

Toyoyuki Kamide

Joined Nomura Trading Co., Ltd. in 1987. Joined Fuji Pharma in 2000.After serving as general manager of the Corporate Headquarters and as managing director of OLIC (Thailand) Limited, he was appointed as director in December 2017.

Outside Director

Tadahiro Kozawa

- President, Inter-Business Associates Corporation
- Outside auditor, Naigai Yakuhin Co., Ltd.
- Outside director, Kokando Co., Ltd.

Brief Biography He established Inter-Business Associates in 1986 and became its president (to present).He has served Fuji Pharma as an outside director since December 2003.

Outside Director

Keiji Hirai

- Corporate Advisor, Kyorin Pharmaceutical Co., Ltd.
- Outside director, Trans Chromosomics, Inc.

Brief Biography He served Kyorin Pharmaceutical as president, representative director and CEO and is currently a corporate advisor.He has served Fuji Pharma as an outside director since December 2016.

Outside Director

Minesaburo Miyake

- Outside director, Kameda Seika Co., Ltd.
- Outside director, Autobacs Seven Co., Ltd. (An Audit and Supervisory Committee Member)
- Chief Associated Member, Council for Utilization of Dormant Deposits, Cabinet Office
- Outside director, FOOD & LIFE COMPANIES Ltd.

Brief Biography After serving Kewpie Corporation as representative director, president and chief executive corporate officer and other posts, he has been serving Nakashimato as chairman and director (to present).He has also served Fuji Pharma as an outside director since December 2017.

Outside Director

Robert Wessman

- Alvotech hf. Chairman of the board
- Alvogen Aztiq AB Director
- Lotus Pharmaceutical Co.,Ltd. Chairman
- Alvotech Holdings S.A. Chairman of the board
- Aztiq Pharma Partners S.a.r.l Director

Brief Biography He became Chairman of the Board of Alvotech hf. in 2012.He has served Fuji Pharma as an outside director since July 2019.

Outside Director

Keiko Kiyama

- Trustee and Secretary General of Japan Emergency NGO (JEN)
- Director of Global Fund for Education Assistance

Brief Biography She co-founded Japan Emergency NGO (JEN) in 1994 and became Trustee and Secretary General of JEN in 2018 (to present). She has also served Fuji Pharma as an outside director since December 2020.

Outside Director

Yukiko Araki

- Executive General Manager, Sustainability Promotion Division, Government & External Relations Group, Hitachi, Ltd.
- Member (part-time) of Administrative Council, Nagaoka University of Technology

Brief Biography She has served as a Corporate Officer at Hitachi, Ltd. from 2015 and became Executive General Manager of the Sustainability Promotion Division, Government & External Relations Group in 2018 (to the present). She has also served Fuji Pharma as an outside director since December 2020.

Audit & Supervisory Board Members

Full-Time Audit & Supervisory Board Member

Seiichi Inoue

Joined the Industrial Bank of Japan, Ltd. in 1983. Joined Fuji Pharma in 2014. After serving as director, managing executive officer and in other posts, he has been a full-time audit & supervisory board member since December 2017 (to present).

Outside Audit & Supervisory Board Member

Fujiaki Mimura

- Partner, Anderson, Mori & Tomotsune (law firm)
- Outside member of the Audit and Supervisory Board, Macnica Fuji Electronics Holdings, Inc.
- Outside auditor, Sanko Marketing Foods Co., Ltd.

Brief Biography Registered with the Tokyo Bar Association in 1987, he is currently a partner of Anderson, Mori & Tomotsune.He has served Fuji Pharma as an outside audit & supervisory board member since December 2003.

Outside Audit & Supervisory Board Member

Miori Sagara

- President and CEO, BAOBAB Inc.

Brief Biography Founded BAOBAB Inc. in 2009 and has since served as its President and CEO, after working for Sumitomo Corporation and others.He has served Fuji Pharma as an outside audit & supervisory board member since December 2019. Founded BAOBAB Inc. in 2009 and has since served as its President and CEO, after working for Sumitomo Corporation and others. He has served Fuji Pharma as an outside audit & supervisory board member since December 2019.

Specialties of Officers

O Outside Officer I Independent Officer

	Name	Management	Global	Technology	Finance	Legal	Healthcare	Sustainability
Directors	Hirofumi Imai	●	●				●	●
	Takayuki Iwai	●	●				●	●
	Takayuki Kasai	●	●	●			●	
	Toyoyuki Kamide	●	●		●			
	Tadahiro Kozawa O I	●	●					
	Keiji Hirai O I	●	●				●	
	Minesaburo Miyake O I	●					●	●
	Robert Wessman O	●	●				●	
	Keiko Kiyama O I	●	●					●
	Yukiko Araki O I	●					●	●
Audit & Supervisory Board Members	Seiichi Inoue	●			●			
	Fujiaki Mimura O I		●			●		
	Miori Sagara O I	●		●	●			●

Sustainability

Sustainability Activities

We are working as a group to implement sustainability activities, with the aim of realizing our goal of "Integrating the world happiest company and social contribution."

Basic Perspective on Sustainability Activities

Fuji Pharma has the corporate philosophy: “We help people lead healthy lives by offering excellent pharmaceuticals.” and “Our corporate growth is proportional to our personal growth.” We believe that the core of our sustainability activities lies in serving society by practicing our corporate philosophy and, in doing so, attaining continued growth.
We are committed to fulfilling our social responsibilities and helping solve social issues, including the improvement of people’s lives through our business activities while considering protection of the environment, the economy and other social sustainability issues.

Basic Policy on Sustainability

Contribution	Every one of us will practice our corporate philosophy by providing the value unique to Fuji Pharma and behaving with constant awareness of contributing to continued development of society.
Growth	We will keep in mind that growth of individual employees leads to the growth of Fuji Pharma and that striving for constant growth helps make greater contribution possible.
Compliance	We will each observe the Code of Conduct regarding Compliance and always think about the right action to take, with the awareness that we are part of society in all aspects of our business activities.
Respect for Human Rights	We dignify and respect human rights and individualities of all people.
Environmental Conservation and Protection	We always keep in mind that environmental resources are limited and proactively work to conserve the global environment.

Initiatives on seven core issues

As a pharmaceutical company which helps people lead healthy lives, we are meeting the increasingly diverse needs of society by practicing our corporate philosophy, and to fulfil our social responsibility, we conduct activities based on an awareness of the seven core subjects covered by ISO 26000.
Below is an explanation of our initiatives classified according to each of the seven core subjects.

E Environmental initiatives S Social initiatives G Governance initiatives

G 1 Organizational governance

For details of organizational governance, please refer to the section on Corporate Governance. ⟹ P. 29

S 2 Human rights

In all our relationships, not only within the Group but with all stakeholders including suppliers of active ingredients, customers and other business partners, we create an environment in which we respect the human rights, personality and individuality of others and do not tolerate unfair discrimination or harassment. We respect the diversity of officers and employees and, through measures such as providing training to clarify company policies for realizing diversity, prevent harassment and instill respect for human rights, we strive to create a workplace characterized by mutual respect aiming to realize a society and workplace that are free from discrimination.

S 3 Labor practices

In line with our corporate philosophy, we believe that continuously creating opportunities and places where employees can display their strengths is an important duty of the management team. We are committed to developing human resources, encouraging women's participation and advancement in the workplace, and implementing health and productivity management initiatives, and will strive to develop a safe and healthy workplace environment.

Promoting women's participation and advancement in the workplace

We aim to facilitate women's participation and advancement in the work place and support the adjustment of work styles according to life events and career goals. We appointed one female Corporate Officer in October 2020 and two female Outside Directors in December 2020 and the percentage of woman in managerial positions stood at 21.3% as of April 2021. Our goal is to increase this ratio to over 30% by March 2024.
In an initiative related to women's health issues, we provided training to increase managers' understanding of women's health issues, thereby improving communication with female employees. By facilitating women's participation and advancement in the work place, we aim to improve our productivity as a company and increase the well-being not only of female employees but across the company as a whole. In addition, as a pharmaceutical company specializing in the women's healthcare domain and aiming to improve the well-being of women around the world, we will continue working to promote women's participation and advancement in the workplace by focusing on the development of systems and a culture which help female employees balance work and child care/ nursing care and make it easier for women to continue working.

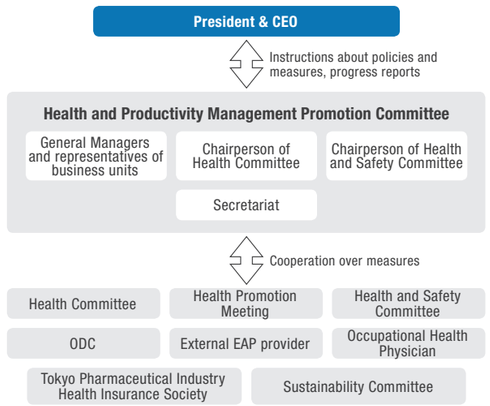
Results and Targets

	September 2020	As of April 2021	March 2024 Target
Percentage of woman in managerial positions	16.9%	21.3%	30%
Number of female Directors	0	2	-
Number of female Corporate Officers	0	1	-
Percentage of employees taking childcare leave	Women 83.3%/Men 16.7%	- (No data available as part way through the fiscal year)	Women 100%/ Men 30% or more

Actions for health and productivity management

We focus on health and productivity management from the viewpoint that creating a workplace environment in which every employee is physically and mentally fit and can work energetically is essential to realize our corporate philosophy. We positioned health and productivity management as a key strategy under our current Mid-Term Business Plan and, in October 2020, we newly established the Health and Productivity Management Promotion Committee to formulate a Health and Productivity Management Declaration and Health and Productivity Management Basic Policy.
In line with our belief that management which values people is Fuji Pharma's foundation, we are committed not only to upholding laws and regulations such as the Industrial Safety and Health Act but also to reducing working hours to a reasonable level, creating a comfortable workplace environment, implementing measures to increase employees' health and maintaining and improving mental health. With respect to mental health, we formulated a mental health action plan and put in place a structure which will allow us to care for employees affected by anxiety and stress as a result of the COVID-19 pandemic.

Health and productivity management implementation structure



Achievement of 2,100 consecutive days without industrial accidents at OLIC

OLIC has been encouraging the monthly reporting of near misses since it launched the project in June 2015. This project proactively encourages employees to report near misses by offering awards to reporters and introduces improvements for at least 50% cases reported each month. It helps make clear the risks in workplaces and prevents industrial accidents through strict implementation of the five-S (Sorting, Setting-in-Order, Shining, Standardizing, and Sustaining the Discipline) practices and facility improvements.
OLIC engages in educational activities in its morning meetings led by the safety management team, quarterly risk prediction training and pre-work safety inspection training to develop employee's awareness of safety. It has an awards program for departments achieving zero accidents and, through company-wide safety efforts, it aims to achieve 2,500 days without accidents as its next target.

E 4 The environment

Fuji Pharma complies with the Act on Rationalizing Energy Use, the Air Pollution Control Act, the Water Pollution Prevention Act, the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof and the standards for emissions of environmentally hazardous substances subject to voluntary control in accordance with agreements with local governments. The Company previously considered and implemented actions required to reduce environmental impact from the development stage in line with its basic position on the environment set out in its Compliance Code of Conduct, which states that "Every employee will seriously consider and implement initiatives to reduce environmental impacts based on an awareness of environmental issues." In addition to this, we formulated an Environmental Policy in April 2021 and reassessed the actions we should take as a company to realize a sustainable society. We will conduct the sustainable corporate activities in accordance with this policy.

Environmental Policy

Fuji Pharma's philosophy consists of "We help people lead healthy lives by offering excellent pharmaceuticals." and "Our corporate growth is proportional to our personal growth." As part of this, we see passing the environment, which is the foundation for human existence, on to the next generation in a better state than we found it as an important management issue and we are committed to conducting business activities that are considerate of the environment with the aim of realizing a sustainable society.

1 Consideration for the environment We will permanently integrate environmental activities into all our business activities, including research and development, procurement, production, logistics, sales and marketing, to save resources, reduce waste and limit the emission of environmentally hazardous substances.

2 Compliance We will comply with environmental legislation and agreements as well as regional and industrial codes of practice.

3 Establishment of environmental management system We will establish an environmental management system (EMS) and review the system regularly to ensure it remains appropriate and valid. We will also build an appropriate structure for operation of the EMS, establishing targets and actions plans, performing monitoring on a regular basis, actively disclosing information and fulfilling our responsibility of explaining our EMS to stakeholders.

4 Mitigation of environmental risk We will focus on the following aspects.
(1) Efficient use of energy and resources
(2) Limitation of waste generation, appropriate waste disposal, and promotion of recycling
(3) Reduction of air and water pollutant emissions

5 Employee education To instil a constant awareness of our impact on the environment and local communities as a pharmaceutical company which helps people lead healthy lives, we will provide employees with ongoing education, teaching them to preserve and protect the environment and raising their environmental awareness.

6 Contribution to local communities We will strive to improve communication with local communities and actively participate in local environmental preservation and protection activities.

S 5 Fair operating practices

We conduct fair corporate activities in accordance with laws and regulations, complying with the Pharmaceutical and Medical Device Act and other relevant laws and regulations and also acting in good faith with common sense as human beings and members of society. Pharmaceuticals have significant effects on the human body and are governed by many regulations specific to the pharmaceuticals industry. We are committed to conducting fair corporate activities, ensuring compliance with these laws and regulations and our own voluntary standards.

For details of our position on compliance, please refer to the section on corporate governance. ⟹ P. 31

S 6 Consumer issues

We provide information about our products in an appropriate manner and strive to manufacture and supply high quality, safe products.

We will investigate which pharmaceuticals are needed by medical professionals to create excellent drugs with high quality and high added value. Fuji Pharma is committed to contributing to health, well-being and healthcare, and we will continue actively working to achieve the stable supply of high quality pharmaceuticals that offer even greater convenience for patients and healthcare professionals.

Efforts to improve group-wide quality control through the implementation of TQC presentation meetings

TQC stands for Total Quality Control and consists of group-wide efforts to control quality. We are constantly working to solve problems and accomplish tasks related to quality control and we hold TQC presentation meetings twice a year as an opportunity for each team to present the results of their TQC activities. Each section of Toyama Plant, the Regulatory Compliance Department and the Supply Chain Management Department forms a team and share the results of their initiatives as a team with the rest of the company. At the 74th TQC presentation meeting held in October 2020, 23 teams took part and 2 teams were selected as recipients of the first prize. The results of an initiative by the Fourth Section of the Second Production Group of the Pharmaceutical Production Department to improve the ampoule filling machine bottle breakage rate, which was one of the initiatives selected for the first prize, was presented at the 6304th QC Club Mini Presentation Conference held by the Toyama Section* of the Hokuriku regional branch for QC clubs and won the "Confirmed firmly by the three realism" prize.

* The Toyama section organization for QC club activities (small group improvement activities) founded by the Union of Japanese Scientists and Engineers. As of FY2020, more than 100 companies belonged to the Toyama Section.

Examples of themes of TQC initiatives

- Reduction of mechanical problems
- Shortening of working hours
- Reduction of workload
- Improvement of quality through elimination of causes of defects and deviation
- Reduction in amount of waste etc.

Presentation by our employee at QC club mini presentation conference

S 7 Community involvement and development

We proactively communicate with all stakeholders to extensively contribute to communities.

Initiatives to raise awareness about women's health

Fuji Pharma has traditionally provided a wide range of pharmaceuticals to treat conditions experienced by women at each life stage. However, given the recent diversification in work styles and changes in lifestyles, we believe that raising awareness to enable women to choose a life plan for themselves and consult with medical institutions or deal with their symptoms based on a correct understanding of the workings of their body and women's issues is also an important responsibility for us as a company dedicated to improving women's well-being. Based on this approach, we mainly implement initiatives such as the following.

Initiative 1 LiLuLa, app aimed at supporting women's health

In July 2018, we released the LiLuLa smartphone app aimed at supporting the health of women of all generations and embarked on educational activities with a view towards improving health literacy. LiLuLa provides valuable information for women on menstruation and other related themes (such as contraception, infertility, gynecological examinations and menopause). To broaden our audience, we also created the LiLuLa website in February 2020, making the information available through the website as well as the app.

There is quite a lot of information available on the Internet which is not reliable. LiLuLa, by publishing articles under the supervision of obstetricians and gynecologists, with the participation of medical professionals specializing in gynecology, is able to provide accurate information.

As part of our health and productivity management, we make LiLuLa awareness-raising activities available to other companies and organizations.

LiLuLa – an app supporting women's health

The app can be downloaded by scanning the above QR Code. We hope you will find it useful.
*QR Code is a registered trademark of DENSO WAVE.

Initiative 2 Support for various seminars about women's health

Recently, we have been supporting seminars and events about women's health organized by other companies or organizations. We believe that supporting high-impact media and events will open the path to an accurate knowledge and understanding among more stakeholders, mainly women, and help improve literacy of society as a whole.

For example, the "Workstyle Reform for Women! 'Seiri Kaiteki Project'," which we supported at the end of 2020, was established by a consortium of companies led by Nikkei BP Intelligence Group. In addition to Fuji Pharma, and another two pharmaceutical companies took part in the project, wanting to support the realization of a society where it is easier for women to work by encouraging a correct understanding of women's bodies and menstruation and improving literacy of society as a whole. The project was featured in a series of online articles on the theme of menstruation and included events such as an online panel discussion with a gynecologist and a celebrity, and drew a huge response from readers and listeners.

In addition, we supported a number of seminars to the public such as an online seminar on the theme of "Women's Life Design and Reproductive Health" organized by Nikkei Inc. Many of the participants in the seminars gave us the impression that their participation in the seminar had made them more interested in their own health and that those who had not consulted a gynecologist before would be more inclined to seek a consultation as a result of the seminar. We plan to continue raising awareness about women's health issues by supporting such activities in the future.

https://www.lilula-web.jp/2487/
The online seminars are available on demand.

Seminars for the general public supported in recent years

Date	Organizer	Theme	Summary
From April 2020	Nikkei BP Intelligence Group	Support for women's health and promotion of women's participation and advancement in the workplace, focusing on menstruation	Workstyle Reform for Women Project entitled "Workstyle Reform for Women! 'Seiri Kaiteki Project'" supporting the realization of a society where it is easier for women to work by promoting a correct understanding of women's bodies and menstruation. Serial publication of awareness-raising articles online and organization of online seminars for the media and the general public.
March 2021	Nikkei Inc.	Women's Life Design and Reproductive Health	Organization of special online seminars for Nikkei Inc.'s NIKKEI Marunouchi Career Juku
March 2021	Spolink Japan	Gynecologists supporting female athletes	Provision of accurate information about women's issues faced by female athletes and explanation of ways to manage health by specialists.
From April 2021 to August 2021 (plan)	Japanese Organization for International Cooperation in Family Planning (JOICFP)	Dissemination of correct information about women's bodies and promotion of consultations with gynecologists	Lectures by gynecologists and three interactive online seminars between specialists and athletes.

OLIC's contribution to the local community

OLIC conducts social contribution activities in Thailand in cooperation with the local authorities, working with an organization in the Ayutthaya District to release fish into the river and donating computers it no longer uses to schools after taking necessary security measures such as wiping all data. From around March 2020, OLIC began manufacturing alcohol gel and sprays, which were in short supply due to COVID-19 pandemic, and provided them free of charge to hospitals, government agencies, schools and temples in the Ayutthaya District.

Both in Japan and overseas, we see a connection with local communities as important for our operating activities and we are committed to social contribution activities to ensure that we continue to grow alongside local communities.

Provision of alcohol gel to Bang Pa-in Hospital

Three-Way Discussion on Sustainability

We aim to achieve sustainable growth by integrating the world's happiest company and social contribution.

Actively promoting women's participation and career advancement in the workplace and recruiting global human resources

Iwai Since our foundation, we have always operated on the basis that it is our social responsibility to contribute to people's health whilst taking environmental, economic and other social issues into consideration, in line with our corporate philosophy: "We help people lead healthy lives by offering excellent pharmaceuticals." Taking this philosophy as our starting point, we incorporated "Integrating the world's happiest company and social contribution" into our Vision for 2030. This means that we aim to create a virtuous cycle in which each and every employee working for Fuji Pharma Group works with a sense of satisfaction and fulfilment, their work contributes to society and is appreciated by society, leading to an even greater growth and enjoyment on the part of employees and I believe that achieving this vision is in itself a way to increase our sustainability as a group.

Amano To achieve this vision, we operate the Sustainability Committee chaired by President Iwai. Originally the CSR Committee, the newly renamed Sustainability Committee formulated the Basic Perspective on Sustainability Activities and Basic Policy on Sustainability under the guidance of the President, who chairs the committee. We formulated this Basic Perspective and Basic Policy and share individual sustainability activities undertaken across the Group on a regular basis to enable all employees to perform their duties based on an awareness of contributing to sustainable growth and the solution of social issues.
In October 2020, the Sustainability Section was newly established as a business unit dedicated to sustainability, and I am the leader of this section. The promotion of sustainability is one of the strategies under our Mid-Term Business Plan and, by September 2024, which is the final fiscal year of the plan, I intend to improve the quality and quantity of groupwide sustainability activities and to speed up the realization of "Integrating the world's happiest company and social contribution". At Fuji Pharma, we conduct a questionnaire about sustainability every year and I feel that, as the years go by, the number of employees with an understanding of sustainability is increasing and the message is getting through.

Actively promoting women's participation and career advancement in the workplace and recruiting global human resources

Wada Under our current Mid-Term Business Plan, we are also actively promoting diversity alongside sustainability. As Manager of the HR Group, which is responsible for achieving various targets related to diversity, I am working to recruit diverse human resources and promote diversity within the company.
I am currently building internal structures to promote women's participation and career advancement as part of this. According to some surveys, women's health issues such as premenstrual syndrome (PMS), dysmenorrhea and menopausal disorder are one of the factors which prevent women's participation and career advancement. However, survey results show that many women see such issues, especially menstruation, as "a given - something they just have to put up with" and that it is still uncommon for women to regard the discomfort they experience during menstruation as a disorder or a particular health concern.
Partly because of such survey results, we decided to provide management training on health conditions specific to women to all our managers. Partly because Fuji Pharma is a company that handles drugs to treat conditions such as dysmenorrhea and menopausal disorder, we also have many employees with some degree of understanding. However, we hope that such training opportunities will help create a workplace environment in which male managers also show understanding for women's health issues, making it easier for female employees to consult their managers. Moving forward, we would also like to give our female employees themselves a more accurate understanding of such conditions and implement a framework through which we can support the treatment of such conditions if necessary.

Iwai There are still many challenges to overcome but, as a company aiming to be No. 1 in Women's Healthcare, we also intend to focus our efforts on promoting women's participation and career advancement, with the HR Group led by Mr. Wada playing a central role.
In recent years, we have also made progress on global recruitment, an area where we were lagging behind. In 2019, we appointed an Outside Director who comes from Iceland, while our new General Manager of the Business Development Department, appointed in 2021, comes from India. I believe that these are important steps for achieving our goal of "Expanding our business to Global Market from Toyama" under Vision for 2030.

Health and Productivity Management also forms part of the Mid-Term Business Plan

Wada Our current Mid-Term Business Plan also sets out an action plan for achieving health and productivity management in addition to diversity. One such health and productivity management target is to be recognized as a "Certified Health and Productivity Management Outstanding Organization". Whilst the purpose of health and productivity management is to create a lively work place environment and continually endeavor to promote the health of the individual employees who underpin the company, the target of gaining recognition will motivate us to implement health and productivity management initiatives.
In October 2020, we established the Health and Productivity Management Promotion Committee and have just started implementing health and productivity management initiatives in an organized fashion. However, issues that need to be addressed in order to gain recognition are already evident and we are currently striving for improvement.

Iwai I recognize that such health and productivity management, rooted in an awareness of the health of employees, is essential for company management. The same is also true of diversity. I believe that, in Japanese society, where the population is clearly decreasing largely because of the low birth rate, sustainable growth cannot be achieved without embracing diversity. I also believe that incorporating the diverse values and ways of thinking of different genders, age groups and nationalities, rather than being bound by existing company norms, will enable us to adapt swiftly and flexibly to changes in the business environment and can help us achieve growth as a company and help our employees achieve personal growth.

As a company "Contributing to well-being of women in the world"

Amano Whilst internal initiatives are important, involvement in activities to raise public awareness -awareness of men and women alike- about women's health is also something we consider important. Our role as a pharmaceutical company has always been to supply pharmaceuticals. However, I want us to move beyond this to also actively engage in activities to raise awareness of health issues. I imagine that, if society had a more in-depth knowledge about women's health issues, more women would make proper use of drugs and consult a gynecology clinic instead of putting up with problems and pain associated with menstruation.
In 2018, we released the LiLuLa smartphone app, developed under the supervision of gynecologists to support women's health. The app disseminates information with the aim of improving health literacy.
Most recently, we have been supporting initiatives such as the Seiri Kaiteki Project sponsored by Nikkei BP Research & Consulting and a special seminar on "Women's Life Design and Reproductive Health" as part of Marunouchi Career Juku sponsored by Nikkei Inc., and we are continuously working on awareness-raising activities aiming to create a society in which women can play an active role in good health.

Iwai Women's participation and career advancement is essential for Japanese society. We see support for women to make their lives easier, such as the Seiri Kaiteki Project, as consistent with our mission of aiming to be "No. 1 in Women's Healthcare" and, as a company "Contributing to the wellbeing of women in the world" under Vision for 2030, we intend to develop supportive environments both inside and outside the company.
There are still many obstacles we have to overcome, including in our activities inside and outside of the company, in order to realize our goal of being "the world's happiest company" In December 2020, we appointed two new female Outside Directors. Both have a great deal of insight into sustainability and I hope that we will work together to overcome these obstacles one by one, taking the opinions and views of outside experts on board more than ever before.

Principal Financial Data for the Past 11 Years

	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
	Non-consolidated			Consolidated							
Net sales (Millions of yen)	19,698	21,623	21,520	25,174	29,215	31,680	34,229	35,387	37,909	36,279	**33,793**
Operating profit (Millions of yen)	3,232	3,565	2,746	3,261	3,173	3,251	3,568	4,314	4,391	4,173	**3,139**
Ordinary profit (Millions of yen)	3,243	3,545	2,698	3,376	3,198	3,099	3,251	4,628	4,472	4,169	**2,983**
Profit attributable to owners of parent (Millions of yen)	1,944	2,204	1,370	2,068	2,078	2,092	2,118	3,301	3,372	2,962	**2,085**
Capital expenditure (Millions of yen)	1,759	3,414	1,693	3,167	1,073	1,694	2,427	1,261	1,109	1,965	**2,965**
Depreciation (Millions of yen)	1,026	1,021	1,211	1,206	1,376	1,768	1,667	1,769	1,976	1,850	**1,774**
R&D expenses (Millions of yen)	1,114	1,516	1,303	1,280	1,769	1,729	1,840	1,825	1,760	2,052	**3,060**
Net cash provided by (used in) operating activities (Millions of yen)	2,168	1,954	1,171	3,630	2,757	589	4,509	3,238	3,773	7,035	**5,770**
Net cash provided by (used in) investing activities (Millions of yen)	(1,404)	(2,288)	80	(6,601)	(1,975)	999	(3,319)	(1,534)	(1,073)	(12,024)	**(2,616)**
Net cash provided by (used in) financing activities (Millions of yen)	(334)	2,497	(835)	3,743	1,293	(4,635)	78	(3,042)	(2,001)	7,265	**450**
Net assets (Millions of yen)	17,833	21,264	22,098	24,066	28,544	28,593	29,226	32,601	35,350	39,363	**39,961**
Total assets (Millions of yen)	24,723	29,757	31,471	39,138	49,027	45,773	48,147	49,551	53,117	60,737	**61,962**
Earnings per share (Yen)	151.05	167.63	97.09	146.48	140.53	137.55	141.64	220.63	112.68	97.04	**66.94**
Book value per share (Yen)	1,385.65	1,506.00	1,565.03	1,704.06	1,826.54	1,912.27	1,953.65	2,178.46	1,181.37	1,263.51	**1,282.43**
Operating margin (%)	16.4	16.5	12.8	13.0	10.9	10.3	10.4	12.2	11.6	11.5	**9.3**
Return on equity (%)	11.4	11.3	6.3	8.6	7.3	7.3	7.3	10.7	9.9	7.9	**5.3**
Return on assets (%)	13.6	13.0	8.8	8.6	6.5	6.5	6.9	9.5	8.7	7.3	**4.9**
Equity ratio (%)	72.1	71.5	70.2	61.5	58.2	62.5	60.7	65.8	66.5	64.8	**64.5**
Dividend per share (Yen)	30.00	37.00	37.00	40.00	44.00	44.00	45.00	48.00	28.00	29.00	**29.00**
Number of employees	501	543	574	1,450	1,469	1,469	1,455	1,480	1,511	1,527	**1,550**

* A two-for-one split of common shares took place on July 1, 2018.
* OLIC became a subsidiary in October 2012.

Consolidated financial statements

Consolidated balance sheets (Millions of yen)

Assets	Previous fiscal year As of September 30, 2019	Fiscal year under review As of September 30, 2020
Current assets		
Cash and deposits	8,494	**12,041**
Notes and accounts receivable - trade	12,944	**11,700**
Merchandise and finished goods	3,437	**3,858**
Work in process	2,539	**2,265**
Raw materials and supplies	4,735	**4,557**
Accounts receivable - other	43	**8**
Other	1,724	**541**
Allowance for doubtful accounts	(0)	**(0)**
Total current assets	33,919	**34,975**
Non-current assets		
Property, plant and equipment		
Buildings and structures	10,888	**11,229**
Accumulated depreciation	(5,770)	**(5,280)**
Buildings and structures, net	5,117	**5,948**
Machinery, equipment and vehicles	8,596	**10,477**
Accumulated depreciation	(6,950)	**(7,029)**
Machinery, equipment and vehicles, net	1,646	**3,448**
Land	919	**897**
Leased assets	4,389	**4,319**
Accumulated depreciation	(2,070)	**(2,567)**
Leased assets, net	2,318	**1,752**
Construction in progress	1,484	**454**
Other	1,358	**1,410**
Accumulated depreciation	(1,126)	**(1,144)**
Other, net	232	**265**
Total property, plant and equipment	11,718	**12,767**
Intangible assets		
Goodwill	1,494	**1,144**
Other	1,805	**1,754**
Total intangible assets	3,300	**2,899**
Investments and other assets		
Investment securities	7,342	**7,000**
Long-term advance payments	2,308	**2,308**
Deferred tax assets	1,288	**1,189**
Other	858	**821**
Total investments and other assets	11,798	**11,320**
Total non-current assets	26,817	**26,987**
Total assets	60,737	**61,962**

Liabilities	Previous fiscal year As of September 30, 2019	Fiscal year under review As of September 30, 2020
Current liabilities		
Notes and accounts payable - trade	4,813	**3,680**
Short-term loans payable	-	**1,000**
Current portion of long-term loans payable	2,840	**1,640**
Lease obligations	530	**516**
Income taxes payable	492	**460**
Provision for bonuses	856	**432**
Provision for directors' bonuses	7	**6**
Provision for sales returns	22	**21**
Other	2,448	**3,246**
Total current liabilities	12,012	**11,004**
Non-current liabilities		
Long-term loans payable	5,530	**7,590**
Lease obligations	2,014	**1,444**
Net defined benefit liability	1,396	**1,548**
Other	418	**413**
Total non-current liabilities	9,360	**10,996**
Total liabilities	21,373	**22,001**
Net assets		
Shareholders' equity		
Capital stock	3,799	**3,799**
Capital surplus	5,841	**5,841**
Retained earnings	29,243	**30,424**
Treasury shares	(78)	**(68)**
Total shareholders' equity	38,804	**39,995**
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(340)	**(650)**
Foreign currency translation adjustment	896	**600**
Remeasurements of defined benefit plans	(0)	**12**
Total accumulated other comprehensive income	556	**(37)**
Non-controlling interests	2	**2**
Total net assets	39,363	**39,961**
Total liabilities and net assets	60,737	**61,962**

Consolidated financial statements

Consolidated statements of income (Millions of yen)

	Previous fiscal year As of September 30, 2019	**Fiscal year under review** **As of September 30, 2020**
Net sales	36,279	**33,793**
Cost of sales	20,483	**18,921**
Gross profit	15,796	**14,872**
Selling, general and administrative expenses	11,622	**11,732**
Operating profit	4,173	**3,139**
Non-operating income	156	**26**
Non-operating expenses	160	**181**
Ordinary profit	4,169	**2,983**
Extraordinary income	4	**4**
Extraordinary losses	212	**69**
Profit before income taxes	3,961	**2,918**
Income taxes - current	1,083	**724**
Income taxes - deferred	(85)	**107**
Total income taxes	998	**832**
Profit	2,962	**2,085**
Profit attributable to non-controlling interests	0	**0**
Profit attributable to owners of parent	2,962	**2,085**

Consolidated statements of cash flows (Millions of yen)

	Previous fiscal year As of September 30, 2019	**Fiscal year under review** **As of September 30, 2020**
Net cash provided by (used in) operating activities	7,035	**5,770**
Net cash provided by (used in) investing activities	(12,024)	**(2,616)**
Net cash provided by (used in) financing activities	7,265	**450**
Net increase (decrease) in cash and cash equivalents	2,243	**3,547**
Cash and cash equivalents at beginning of period	6,251	**8,494**
Cash and cash equivalents at end of period	8,494	**12,041**

Corporate Profile

Company Name	Fuji Pharma Co., Ltd.
Main Businesses	Development, manufacturing and sales of pharmaceuticals used with prescriptions or guidance (injections, medicines for internal use and for external use and diagnostic drugs)
Head Office	6th Floor, Seitoh Kaikan, 5-7 Sambancho, Chiyoda-ku, Tokyo 102-0075 Japan
Date of Establishment	April 1965
Capital	3,799.1 million yen
Number of Employees	Consolidated:1,540 (778 at Fuji Pharma and 762 at OLIC) (as of March 31, 2021)

Officers (as of March 31, 2021)

Chairman and Representative Director	Hirofumi Imai
President & CEO	Takayuki Iwai
Director, Vice President	Takayuki Kasai
Director, Executive Corporate Officer	Toyoyuki Kamide
Outside Director	Tadahiro Kozawa
Outside Director	Keiji Hirai
Outside Director	Minesaburo Miyake
Outside Director	Robert Wessman
Outside Director	Keiko Kiyama
Outside Director	Yukiko Araki
Full-Time Audit & Supervisory Board Member	Seiichi Inoue
Outside Audit & Supervisory Board Member	Fujiaki Mimura
Outside Audit & Supervisory Board Member	Miori Sagara

Share Information (as of March 31, 2021)

Total number of issuable shares	56,440,000
Total number of issued shares	24,753,800
Number of shareholders	5,654

Major Shareholders (as of March 31, 2021)

Name	Number of shares held	Shareholding ratio (%)
FJP Ltd.	4,332,200	17.82
Hirofumi Imai	4,052,750	16.67
The Master Trust Bank of Japan, Ltd. (trust account)	1,349,600	5.55
Noriko Arai	1,240,000	5.10
Lotus Japan Holdings G.K.	1,219,300	5.02
Custody Bank of Japan, Ltd. (trust account)	1,111,809	4.57
Michiko Imai	846,000	3.48
BBH FOR FIDELITY LOW-PRICED STOCK FUND (PRINCIPAL ALL SECTOR SUBPORTFOLIO)	635,866	2.62
Custody Bank of Japan, Ltd. (trust account 9)	540,800	2.22
Fuji Pharmaceutical Co., Ltd, ESOP	319,780	1.32

Notes:
1. Fuji Pharma holds443,379 treasury shares, which account for1.79% of the total issued shares.
   The treasury shares are excluded in the above calculation of shareholding ratios.
2. Apart from the shareholders mentioned above, Sumitomo Mitsui Trust Bank, Ltd. holds 23,609 shares as trust assets in the officer share ownership plan.These shares are treated as treasury shares on the consolidated balance sheets.

Distribution (as of March 31, 2020)