BRIDGE REPORT Bridge Salon

President Kiyoshi Eshima

Delta-Fly Pharma, Inc.(4598)

Corporate Information

Exchange	TSE Mothers
Industry	Pharmaceutical products (manufacturing industry)
President	Kiyoshi Eshima
Address	37-5 Nishikino, Miyajima, Kawauchi-cho,Tokushima-shi, Tokushima
Year-end	End of March
URL	https://www.delta-flypharma.co.jp/index.html

Stock Information

Share Price	Shares Outstanding		Total Market Cap	ROE(Actual)	Trading Unit
¥1,649	4,504,600 shares		¥7,428million	-56.0%	100 shares
DPS(Estimate)	Dividend Yield (Estimate)	EPS(Estimate)	PER(Estimate)	BPS(Actual)	PBR(Actual)
¥0.00	-	¥-188.70	-	¥456.47	3.6 times

*Share price is as of closing on May 28. The numbers were taken from the brief financial report for the term ended March 2020.

Earnings Trends

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
Mar. 2017 (Actual)	902	328	323	305	88.31	0.00
Mar. 2018 (Actual)	150	-243	-244	-246	-71.20	0.00
Mar. 2019 (Actual)	-	-592	-671	-673	-170.16	0.00
Mar. 2020 (Actual)	100	-1,545	-1,552	-1,555	-348.32	0.00
Mar. 2021 (Estimate)	300	-850	-850	-850	-188.70	0.00

*Unit: million yen, yen

*The estimated values were provided by the company. 500-for-1 share split was conducted on Jun. 25, 2018. EPS was adjusted retroactively.

This report introduces earnings trends, progress of the development etc. of Delta-Fly Pharma, Inc.

BRIDGE REPORT Bridge Salon

Table of Contents

Key Points

- **The company develops anticancer drugs under the original concept of "module drug development," which means that they develop new anticancer drugs that have an improved balance between clinical efficacy and safety and whose side effects are weak, by using the existing active substances with anticancer property as "modules (components)" and designing dosage and administration, combination methods, etc. with ingenuity.**

- **"Module drug development" has benefits for patients, including the improvement of treatment effects, the elimination of side effects, and cost reduction, and also benefits for development, including the high exclusiveness in patenting, the swiftness of development, and low development risk. The company currently has 6 drug pipelines, and 4 candidate drugs are under clinical tests, and for the other 2 candidate drugs, clinical tests are being prepared.**

- **In addition to module drug development, the company is characterized by the specialization in development of anticancer drugs, the development by experienced members, and efficient business operation utilizing external resources.**

- **In the term ended March 2020, the company posted a business revenue of 100 million yen from lump-sum contract payment for the licensing contract with Nippon Chemiphar Co., Ltd. Further, R&D expenses increased due to the rise in the number of registered cases and medical institutions involved in clinical tests of drug pipelines and because the company proceeded with the manufacture of active pharmaceutical ingredients and preparations for the next test, which will become study drugs. Operating loss was 1,545 million yen, up 953 million yen year on year.**

- **As for the business revenue in the term ending March 2021, the company expects to earn 300 million yen as milestone compensation for licensing contracts. The company expects to finish the clinical phase I test of DFP-14927 in the U.S. while further increasing case registration of DFP-10917 clinical phase III test in the U.S.**

- **Further, as the case registration of domestic DFP-14323 clinical phase II test was finalized, the company plans to make preparations, conducting the next clinical phase III test (large-scale controlled trial) jointly with China's pharmaceutical companies. Also, as for DFP-17729, for which the company has a partnership with Nippon Chemiphar Co., Ltd., it plans to start domestic clinical tests and will proceed with the development of these drug pipelines. As the company had manufactured active pharmaceutical ingredients and preparations in the previous term earlier than planned, it expects R&D expenses to decrease.**

- **For DFP-10917, whose development is making the most progress among the company's pipelines, the company is increasing patients' registrations for its clinical phase III test and the number of facilities that conduct clinical trials in the U.S. Clinical tests were affected by the spread of the new coronavirus in some medical institutions, however, clinical tests in medical institutions located in less-affected regions were continued and there are apparently no major delays at the moment.**

- **Moreover, the company is making steady progress with the development and commercialization of each pipeline. As for DFP-17729, which is expected to be released in the market soon, the company formed a licensing contract with Nippon Chemiphar Co., Ltd. and started preparing for domestic clinical tests. We will continue to pay attention to each release.**

1. Company Overview

Delta-Fly Pharma upholds the corporate ethos: "To provide treatment methods recommendable to cancer patients among relatives with peace of mind, by diagnosing all states of cancer patients rather than seeing only cancer," and develops anticancer drugs under the original concept of "module drug development," which means that they develop new anticancer drugs that have an improved balance between clinical efficacy and safety and whose side effects are weak, by using the existing active substances with anticancer property as "modules (components)" and designing dosage and administration, combination methods, etc. with ingenuity.

1-1 Corporate history

The President Eshima, who was born in Tokushima Prefecture, graduated from Nagoya Institute of Technology, completed the master's course of Tokyo Institute of Technology, and joined the Otsuka Group, a pharmaceutical company in Tokushima Prefecture, which is his hometown. Then, he was assigned to TAIHO Pharmaceutical Co., Ltd., which is a business company of the Otsuka Group.
Immediately after joining the company, he was dispatched to Faculty of Science and Engineering, Waseda University, and engaged in the development of pharmaceuticals, especially new medicines composed of functional polymers, as a researcher for about 12 years. When he was in the section that seeks seeds of pharmaceutical products in TAIHO Pharmaceutical, he saw how the business administration of U.S. bio ventures was carried out. That stirred his willingness to become independent, manage a pharmaceutical company by himself, and create medicines with a new approach, rather than engaging in development in the R&D section of a leading pharmaceutical company. He also aimed to develop a business while not only creating medicines, but also considering what he can do for patients in front of him. In 2010, when he was 61 years old, he resigned from TAIHO Pharmaceutical, and established Delta-Fly Pharma. The company is committed to the development of anticancer drugs whose side effects are weak and friendly to patients through module drug development. As of September 2019, the company has 6 drug pipelines.
It was listed in Mothers of Tokyo Stock Exchange in October 2018.

1-2 Corporate ethos and management philosophy

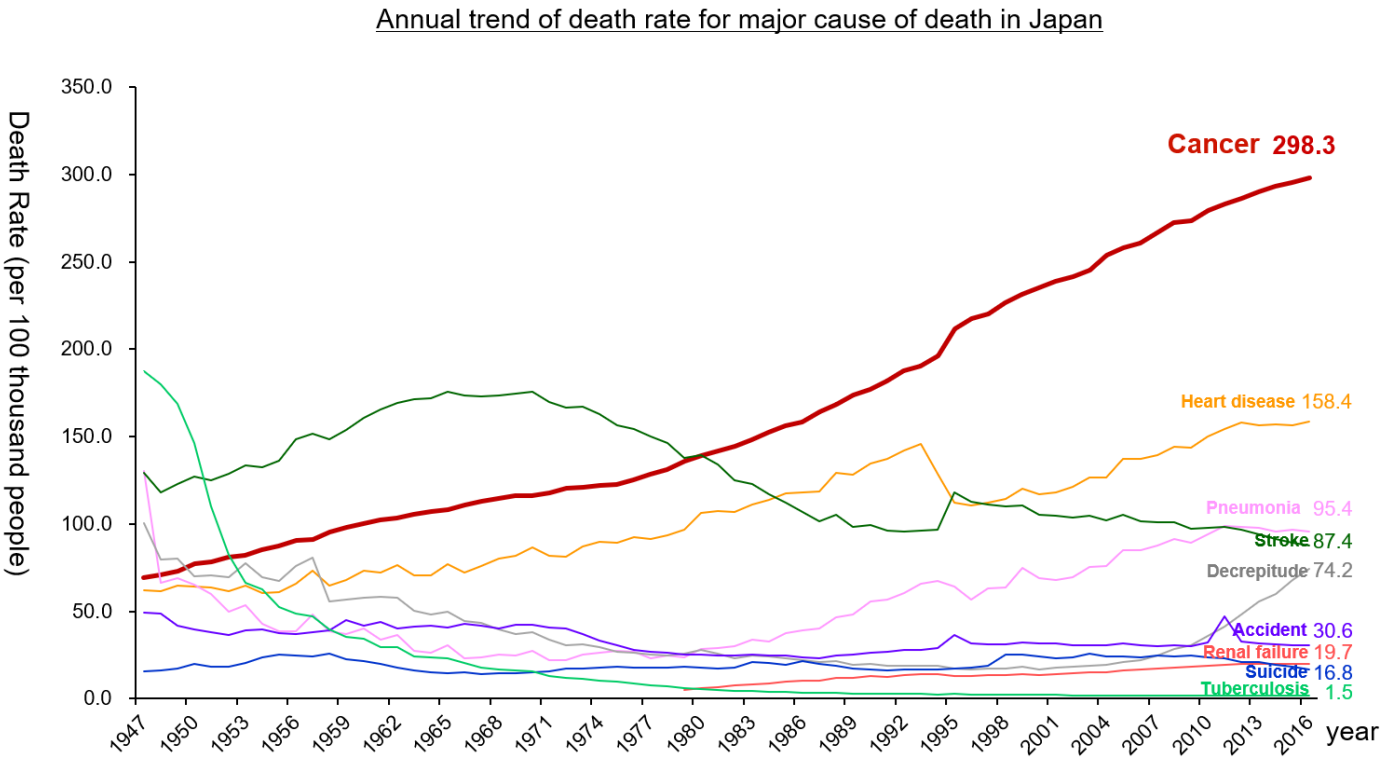
The corporate name "Delta-Fly" is derived from a "dragonfly." Since dragonflies only go forward, and do not go backward, they represent the unflagging spirit, and they are also called "winning insects." Namely, the corporate name implies the firm resolve to develop pharmaceutical products.

Corporate ethos	To provide treatment methods recommendable to cancer patients among relatives with peace of mind, by diagnosing all states of cancer patients rather than seeing only cancer

As mentioned later, the company considers that its social mission is not to develop anticancer drugs only for eradicating "cancer," but to provide anticancer treatment with reasonable price while curbing side effects, which are serious issues with anticancer drugs, so that patients and their family members can use it without worry.

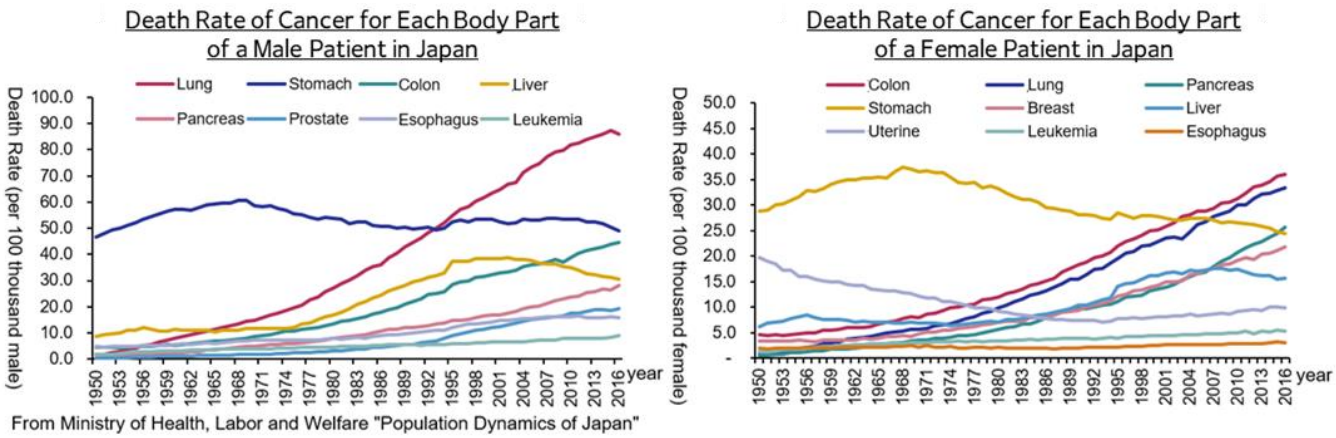
1-3 Environment surrounding the company

According to "the demographic statistics in Japan in 2018" published by the Ministry of Health, Labor and Welfare, the mortality rate (number of deaths per 100,000 people) of malignant neoplasm (cancer) was the highest: 298.3 in 2016. It has been the highest for over 30 years since it replaced cerebrovascular disease, whose mortality rate was 134.3 while that of malignant neoplasm was 142.0, in 1981. It is increasing year by year.
It is said that the incidence of cancer is growing due to the aging of the population, the change in lifestyles, including dietary habits, etc.



From Ministry of Health, Labor and Welfare "Population Dynamics of Japan"

(Taken from the reference material of the company)



From Ministry of Health, Labor and Welfare "Population Dynamics of Japan"

(Taken from the reference material of the company)

In these circumstances, various anticancer drugs are used, and new medicines are being developed. But, as publicly known, the side effects of anticancer treatment are significant, so there are considerable needs for the reduction of side effects from the viewpoint of improving the quality of life (QOL) of patients.

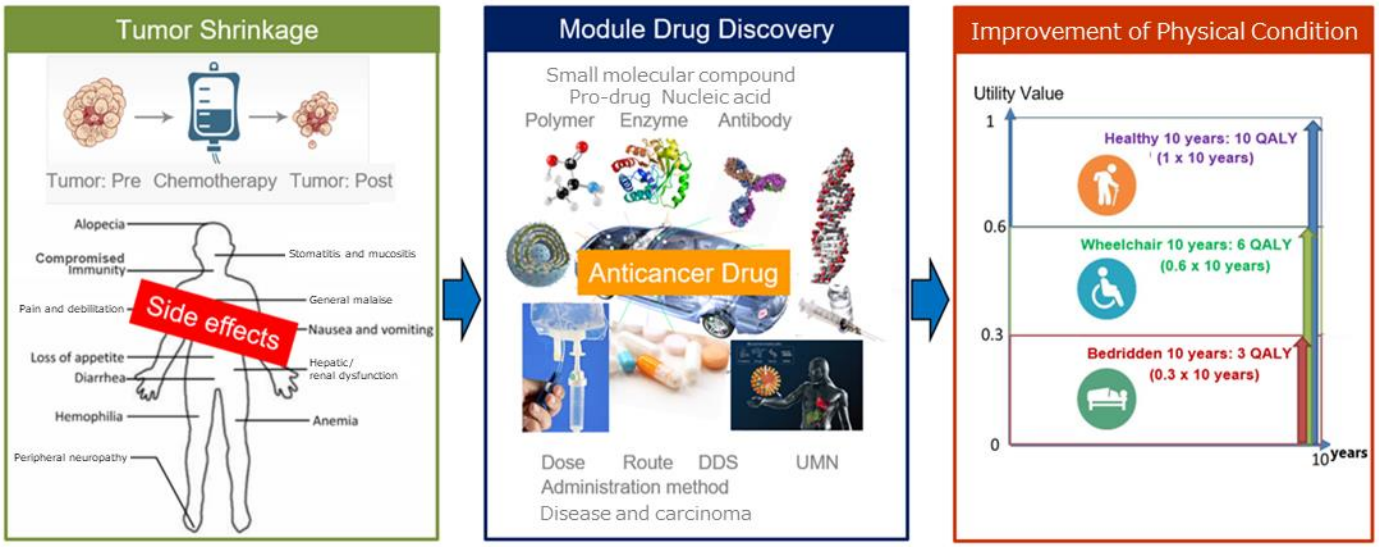
(Mechanism of side effects)

Since cancer cells rapidly divide and proliferate, anticancer drugs are designed to kill rapidly growing cancer cells. However, anticancer drugs affect not only cancer cells, but also the normal cells that rapidly divide, such as blood cells produced in bone marrow, the cells of digestive organs, the cells of genitals, and hair root cells, causing side effects, such as nausea, vomiting, hair loss, and fatigue.

1-4 Business contents

1-4-1 Delta-Fly Pharma's method for creating medicines: Module drug development

What distinguishes the company most among a lot of bio ventures is its concept for developing medicines: "module drug development."



(Taken from the reference material of the company)

"Module drug development" means the development of new anticancer drugs that have an improved balance between clinical efficacy and safety by using the existing active substances with anticancer property as "modules (components)" and designing dosage and administration, combination methods, etc. with ingenuity.

Through "module drug development," the company focuses on not only "cancer circumstances" but also the whole conditions of "cancer patients," improves the anticancer drugs whose effects are limited and which have various side effects in a multifaceted manner, and produces medicines whose side effects are so weak that you can recommend them to your relatives suffering from cancer.

(Advantage of module drug development)

Merits for patients	・Since medicines are created based on data on patients, treatment effects are expected to improve. ・Since medicines are created based on data on patients, conventional side effects are expected to disappear. ・The number of fundamental and clinical tests is small and their periods are short; accordingly, their costs are not considerable.
Merits for development	・Since medicines can be patented due to novelty and inventive steps, they will have high exclusivity. ・Since medicines are developed based on data on patients, development speed is high. ・Since medicines are developed based on data on patients, development risk is low.

In general creation of anticancer drugs, chemicals that act on the cancer-specific parts are extracted at the stage of fundamental search and research, and possible chemicals become candidates for anticancer drugs. However, it is necessary to check their functions at the clinical stage and demonstrate efficacy and safety through clinical tests. Accordingly, the R&D period from the basic stage is long.

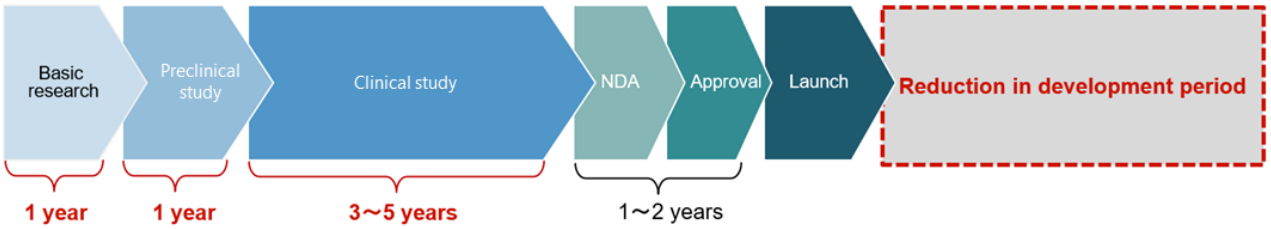
Meanwhile, "module drug development" does not require fundamental search or research so much, because the active substances of already used anticancer drugs are combined, and it is possible to predict efficacy and safety at the clinical stage. Accordingly, it is possible to start clinical tests in one to two years after the start of medicine development. Like this, compared with general development of anticancer drugs, the R&D is more efficient, the development period is shorter, and the risk of development, including the failure in clinical tests, is lower.

In addition, when focusing on the issues with the treatment of cancer patients, the combination of off-patent pharmaceutical products by utilizing the knowledge and know-how of anticancer drugs enables them to be patented as new anticancer drugs

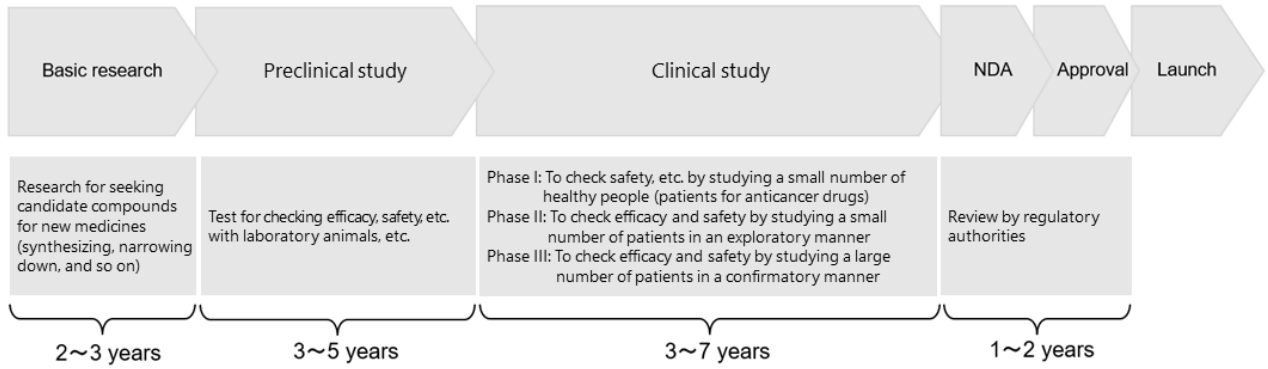
The company's drug development process

■ Compared with the general development process for anticancer drugs, **basic research is almost unnecessary**, because module drug discovery is a method to combine active substances for anticancer drugs which are already used as pharmaceutical products.

■ Because it enables prediction of clinical efficacy and safety, it reduces the research & development period compared to general anticancer drug development, and **reduces development risks of failure at clinical study**.



General drug development process



■ In general, the development of a single pharmaceutical product costs a long period of about 10 to 15 years and enormous funds of several billions to tens of billions of yen.

■ In development of pharmaceutical products, there is significant risk of stopping development due to various factors at each stage until approval. Accordingly, pharmaceutical companies and ventures around the world are facing the big challenge of streamlining the R&D process and reducing development risk.

(Taken from the reference material of the company)

Nowadays, an increasing number of pharmaceutical companies engage in drug-repositioning activities to discover new effects of generic and existing medicines, for the purpose of reducing the cost for new drug development.
These are the same as "module drug development" in that existing medicines are used, but it is difficult to patent these drugs based on generic medicines and drug repositioning because of the lack of novelty and inventiveness. On the other hand, "module drug development" will make all developed drugs patented. This is a defining difference.

As long as they try to solve the problems with anticancer drugs, they can create totally new anticancer drugs. Therefore, the company is certain that "module drug development" will bring significant innovation to methods for creating medicines.

1-4-2 Business and revenue models

(Business model: to develop an efficient R&D system)

Before a new pharmaceutical product is released, it is common that "fundamental research" is first conducted, "preclinical tests (tests for checking the pharmacological actions, in-vivo kinetics, harmful effects, etc. by using animals)" and "clinical tests (scientific tests for studying the effects of pharmaceutical products, treatment technologies, etc. on human bodies)" are carried out, applications are submitted to authorities to obtain approvals, products are manufactured, and then surveys are conducted after manufacturing, marketing, and sale.

In these processes, Delta-Fly Pharma concentrates on the management of R&D, while outsourcing meticulous tasks to excellent external R&D companies and manufacturers inside and outside Japan. The company has actualized an efficient R&D system in cooperation with external cooperative institutions according to development phases. It also engages in the R&D for new anticancer drugs by using a drug delivery system in collaboration with Sanyo Chemical Industries, Ltd. (1st section of TSE; 4471).

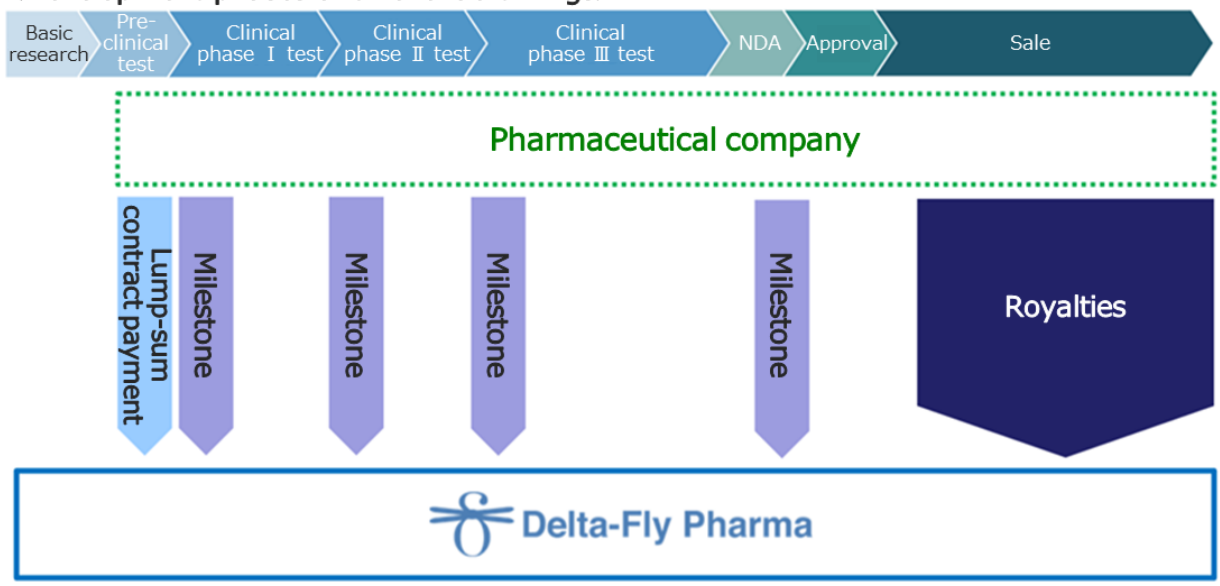
(Revenue model)

At the R&D stage, the main revenue sources are "lump-sum contract payment" for contracts with affiliated pharmaceutical companies, "milestone," and "cooperation funds for development." If collaborative products are released, the company will receive royalties according to sales.

Currently, Delta-Fly Pharma collaborates with the following three pharmaceutical companies.

Kyowa Chemical Industry Co., Ltd. (unlisted)	Signed a contract for an exclusive license for the candidate compound for anticancer drugs DFP-14323 in Japan.
Nippon Shinyaku Co., Ltd. (1st section of TSE, 4516)	Signed a contract for an exclusive license for the candidate compound for anticancer drugs DFP-10917 in Japan.
Nippon Chemiphar Co., Ltd. (1st section of TSE, 4539)	Signed a contract for an exclusive license for the candidate compound for anticancer drugs DFP-17729 in Japan.

<Development phases and revenue timings>



<Major sources of revenue>

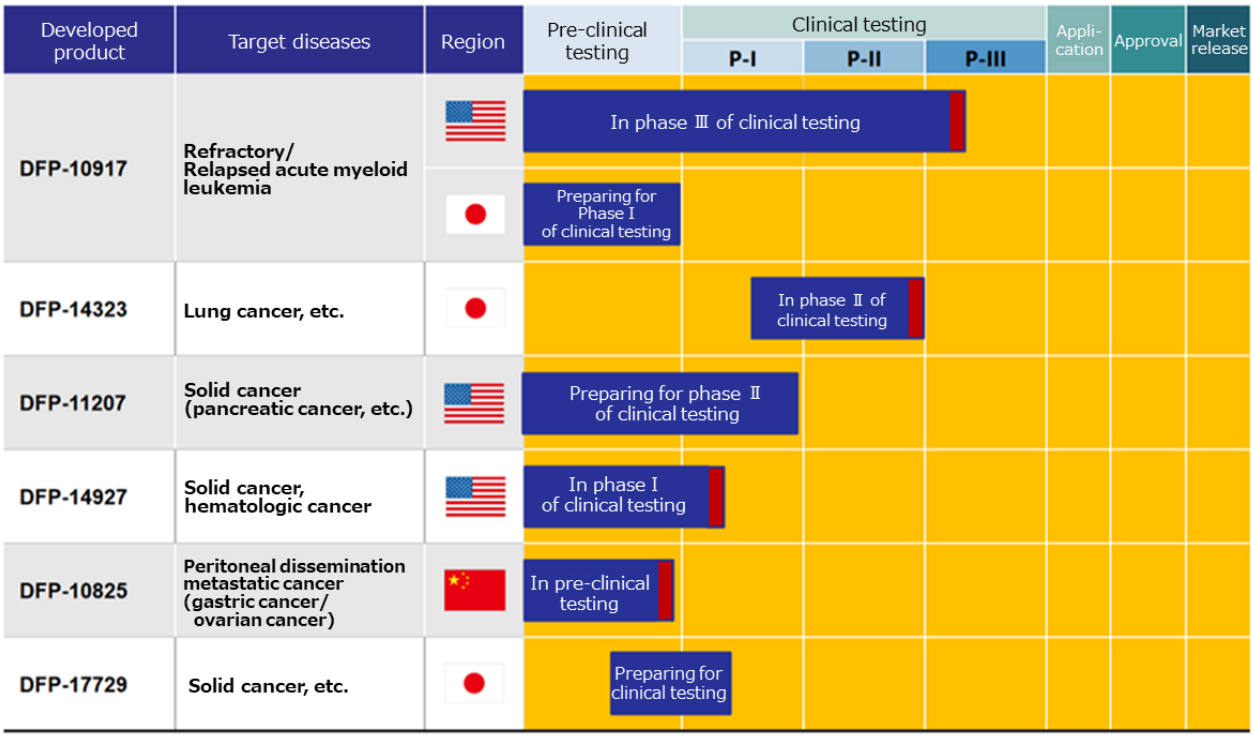
Revenue	Details
Lump-sum contract payment	Revenue received as lump-sum contract payment
Milestone	Revenue from achieving pre-planned events according to the R&D progress

Revenue	Details
Development cooperation expenses	Revenue affiliate companies cover according to R&D expenses
Royalties	Revenue received according to sales of released pharmaceutical products

(Taken from the reference material of the company)

1-4-3 Drug pipelines

As of now, Delta-Fly Pharma has the following 6 drug pipelines in accordance with the above mentioned management policy.
The progress, current situation, and future plan for the development and commercialization of each pipeline are as shown below. Four candidate drugs are undergoing clinical tests. For the remaining two candidate drugs, clinical tests are being prepared.



(Taken from the reference material of the company)

1)「DFP-10917」

Item	Outline
Main target disease	Refractory and recurrent acute myeloid leukemia. The number of deaths associated with acute myeloid leukemia is 10 thousand in Japan, 30 thousand in the U.S., 30 thousand in Europe, and 20 thousand in China. 85% of the people who died from leukemia were 60 years old or older. (Standard treatment methods have been established. About 70% of patients go into remission temporarily, as the cancer cells disappear from blood, but recurrence rate is high, and only 30% of patients can recover fully.)
Characteristics of existing medicines, etc.	The existing medicine CNDAC is targeted at solid tumors. Dosage is high, and administration is conducted intravenously or orally in a short period of time. The efficacy against solid tumors is limited, and serious side effects were observed in some cases.
Improved points and effects of modules	The dosage was reduced, and administration was conducted intravenously and continuously for a long period of time. As a result, there emerged different effects from those of conventionally used nucleic-acid derivatives (such as cytarabine and gemcitabine). It can be expected that the drug will be effective for the patients of refractory and recurrent acute myeloid leukemia, which cannot be treated with existing chemotherapy.
Countries where patents were acquired (as of the end of May. 2020)	Japan, the U.S., EU, China, Australia, South Korea, and Russia

(State of development, and future commercialization)

In the clinical phase I/II tests carried out in the U.S., the drug was effective for 48% (14/29) of patients in the phase II, indicating high effectiveness. Seeing this result, the company had a meeting with the U.S. Food and Drug Administration (FDA) after the clinical phase II test, and submitted a plan for the clinical phase III test. Consent was obtained, however, as the treatment system of refractory and recurrent acute myeloid leukemia was changed, part of the protocol for Phase III clinical testing was changed before re-submitting it to the US FDA. Phase III of clinical testing started. A startup meeting was held, and the screening of research subjects started. In November

2019, two case registrations were made.

The company aims to complete the phase III test by fiscal 2021, and obtain approval and sell it in the U.S. by fiscal 2022. As for Japan, the licensee, Nippon Shinyaku Co., is preparing for phase I of clinical testing. Also, the company received advice from Pharmaceuticals and Medical Devices Agency face-to-face.

(Patent-related)

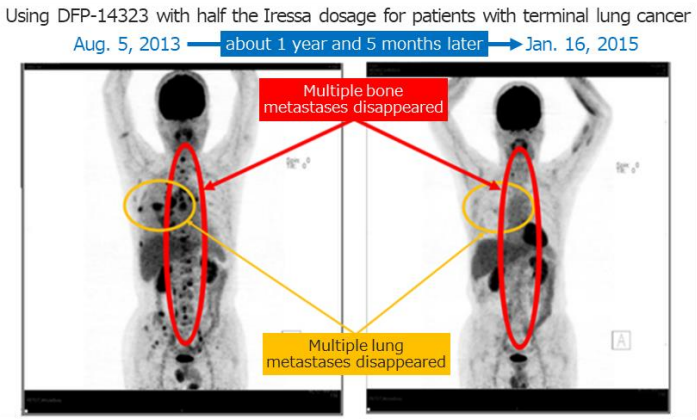
In May 2020, the company submitted a substance patent for the new derivative of Venetoclax, which is planned to be used with DFP-10917.

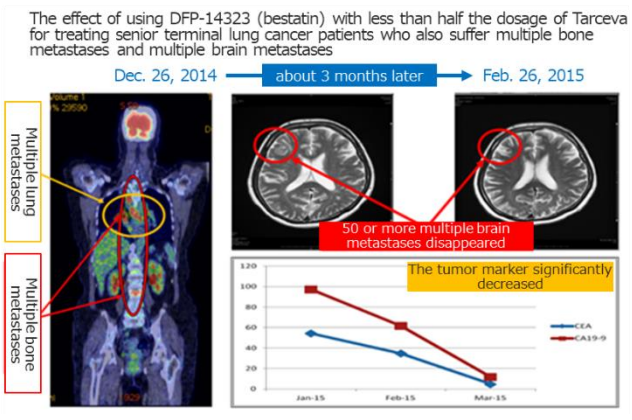
The new derivative of Venetoclax, for which the company submitted a patent, is a new substance acquired by forming a covalent bond between Venetoclax and a water-soluble polymer, and can selectively transport the active substance of Venetoclax to the targeted cancer cells; in experiments on animals transplanted subcutaneously human acute myeloid leukemia cells, it indicated similar results to the existing Venetoclax with less than a few tenths of the dosage while being safer.

2)「DFP-14323」

Item	Outline
Main target disease	Terminal stage lung cancer, etc.
Characteristics of existing medicines, etc.	The existing medicine "bestatin (Ubenimex)" is targeted at blood cancer. The dosage is high, and administration is conducted intravenously or orally with a single agent. It is indicated that the drug is for blood cancer only, but it showed a survival advantage against lung cancer.
Improved points and effects of modules	For the purpose of enhancing the antitumor effect, the dosage was reduced, and the drug was used together with a molecular target drug. As a result, the efficacy against lung cancer was confirmed. The drug is expected to improve the immune function of cancer patients, and treat terminal or elderly patients of solid tumors.
Countries where patents were acquired (May. 2020)	Japan, the U.S., EU, Australia, Russia, Korea, China

◎Confirming the clinical efficacy of DFP-14323





(Taken from the reference material of the company)

(State of development, and future commercialization)

As for the existing medicine Ubenimex, Nippon Kayaku Co., Ltd. obtained the approval for its efficacy and effect of "prolonging the survival period of adults suffering from acute non-lymphatic leukemia when combined with maintenance and intensive chemotherapeutic agents after remission" in Japan.

Delta-Fly started the clinical phase II test for the combined treatment of low-dose EGFR-TKI targeted at patients of EGFR gene mutation-positive non-small cell lung cancer as an additional indication in January 2018 in Japan and since the facilities that conduct clinical trials have increased in Japan, the company proceeded with registering new cases. In March 2020, the registration was complete for all cases.

Later, although the effect is still being judged based on the Disease Control Rate (DCR) of all registered cases (including ones of brain metastases), in April of the same year, it confirmed meeting the efficacy standards (87% or higher) for clinical phase III test (large-scale controlled trial) and plans to advance to clinical phase III test (large-scale controlled trial).
The company is going to start clinical phase III test (large-scale controlled trial) early and it plans to do it jointly with pharmaceutical companies in China, which has a high interest in DFP-14323.

It expects to finish evaluating the efficacy of all cases by the end of May 2020 and in order to improve the quality of the data of trials, the company will ask an independent doctor (specializing in radiology), who wasn't engaged in the clinical phase II test, to perform an efficacy evaluation in June.
Furthermore, it will make a presentation about the details of the clinical data in ESMO Asia Congress 2020 (The European Society for Medical Oncology), which is to be held in Singapore in November. If progress goes favorably, the company aims to obtain an approval for an additional indication and start sales in Japan by FY 2023.The company has concluded a contract for an exclusive license in Japan with Kyowa Chemical Industry Co., Ltd. (unlisted)

(Patent-related)
In May 2020, a patent was granted in Europe.
Currently, they have a pending patent application for DFP-14323 in the People's Republic of China and are following up on the evaluation process with the China National Intellectual Property Administration. When the patent is granted in the People's Republic of China, the company will have a foundation for expanding its business globally to major countries.

3)「DFP-11207」

Item	Outline
Main target disease	Solid tumors (such as pancreatic cancer)
Characteristics of existing medicines, etc.	The existing medicine TS-1 has hematotoxicity, including the reduction of blood platelets, and it is difficult to continue treatment sufficiently.
Improved points and effects of modules	DFP-11207 is a compound developed by combining three modularized active substances (modules I, II, and III) for sustained release, inhibition, and deactivation, in order to control the pharmacokinetics of 5-fluorouracil (5-FU), which has anticancer effects. It avoids hematotoxicity, including the decrease of blood platelets, which is caused by conventional 5-FU anticancer drugs, improves the balance between efficacy and safety, and enables long-time continuous treatment. This is a representative case of module drug development, in which the combination of compounds was improved.
Countries where patents were acquired (May. 2020)	Japan, the U.S., EU, China, Australia, Korea, Russia, Republic of China, Hong Kong

(State of development, and future commercialization)
In the U.S., the company proceeded with the clinical phase I test for solid tumors (digestive system cancer), and checked the recommended dose at the next test and confirmed that the decrease of blood platelets does not occur as a side effect, which has been caused by conventional 5-FU anticancer drugs.
Currently, the preparations are progressing as testing the effects of food has finished, and the company summarized the process, held a discussion with the clinical investigators, and formulated the plan for phase II of clinical testing with the combined use of anticancer drugs.

The company announced the results of phase I of clinical testing and the study of food effects at the conferences of the Chinese Society of Clinical Oncology (CSCO) and Japan Society of Clinical Oncology (JSCO).
Moreover, in May 2020, the company's paper of the clinical phase I results in the U.S. was published in the American cancer treatment journal "Investigational New Drugs." The drug's safety was confirmed as it does not cause diarrhea or platelet toxicity, does not require a withdrawal period, and leukopenia is mild, and it was recognized as a drug that could have a life-extending effect.
The company is negotiating with Chinese pharmaceutical companies interested in these American clinical data to open up opportunities

for joint development between the U.S. and China.

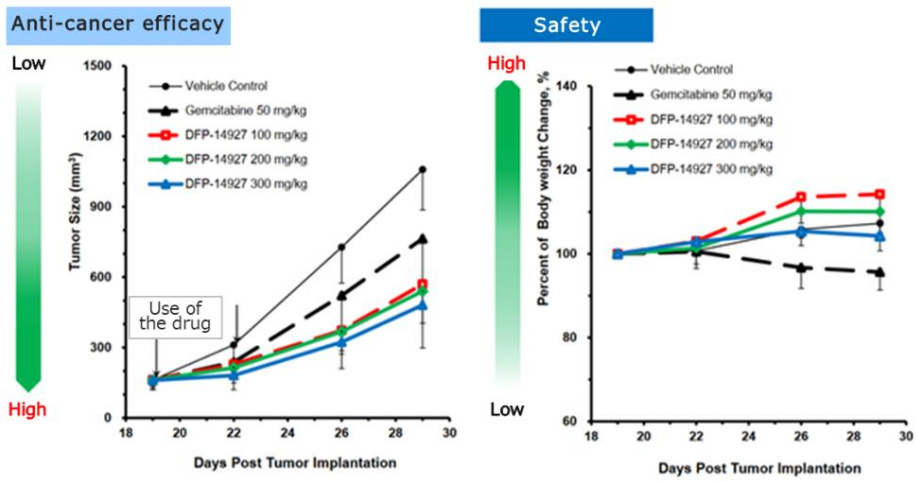
It aims to obtain approval and sell it in the U.S. or in China by fiscal 2024.

4)「DFP-14927」

Item	Outline
Main target disease	Pancreatic cancer, gastric cancer, and myelodysplastic syndromes
Characteristics of existing medicines, etc.	The existing medicine DFP-10917 needs to be administered for 14 days in a row, by using a pouch for continuous intravenous injection, and it was necessary to improve its convenience. The target disease has been only blood cancer.
Improved points and effects of modules	DFP-14927, a polyethylene glycol-conjugated candidate anticancer substance, is a polymeric delivery of DFP-10917. It selectively clusters around cancer tissue, and discharges DFP-10917 effectively inside cancer cells. The frequency of administration was reduced to once per week, and intravenous drip infusion was adopted. As a result, the medicine now can be used against solid tumors and myelodysplastic syndrome as well as blood cancer. Additionally, in animal models with pancreatic cancer, it was confirmed to be more effective and safer than gemcitabine, the standard chemotherapy for pancreatic cancer.
Countries where patents were acquired (as of the end of May. 2020)	Japan, the U.S., China, Australia, Russia

◎Confirming DFP-14927 efficacy on animals

In animal models of pancreatic cancer, both the efficacy and safety of DFP-14927 were higher than gemcitabine, the standard chemotherapy for pancreatic cancer.



(Taken from the reference material of the company)

(State of development, and future commercialization)

The preclinical test has been finished in the U.S. The data of the preclinical test indicate that the level of the medicine in blood is stable for a long period of time when it is administered once a week, and that there is the antitumor effect against solid tumors.

In March 2018, the company concluded a contract for collaborative development with Sanyo Chemical Industries, Ltd. and prepared for the application for the start of the clinical phase I test, and on January 18, 2019, the U.S. FDA completed the examination of the safety of Investigational New Drug (IND), and approved the clinical phase I test in the U.S. And the company started clinical phase I testing aimed at patients with digestive system cancer including pancreatic cancer and gastric cancer.

2 case registrations have been made since October 2019.

In addition to the clinical test, the company plans to discuss the possibility of administration to patients of blood cancer, including myelodysplastic syndrome.
They aim to obtain approval and start sales in the U.S. by FY 2025.

5)「DFP-10825」

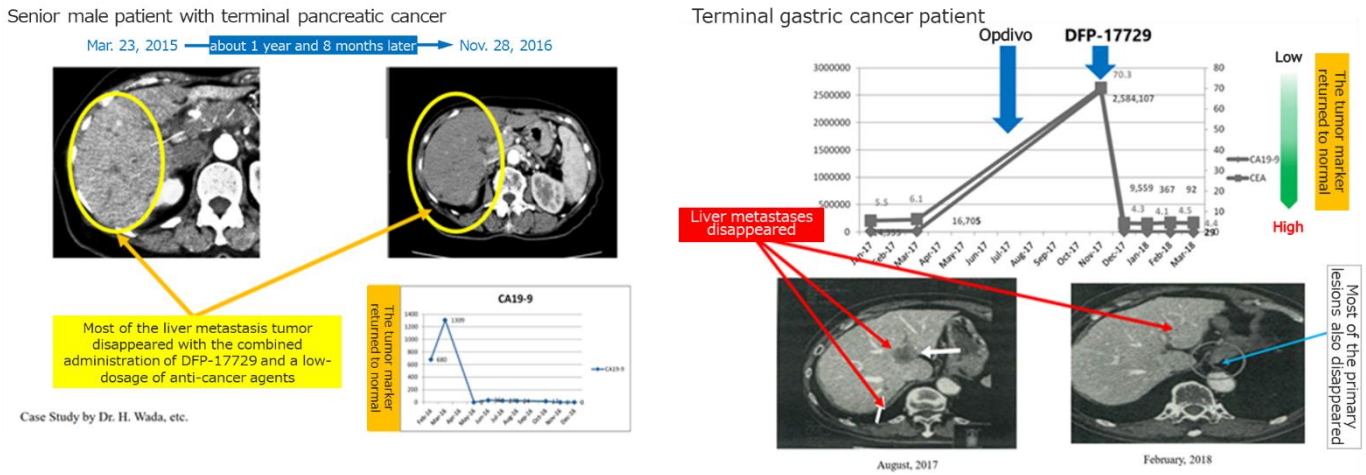
Item	Outline
Main target disease	Gastric cancer, ovarian cancer, and peritoneal metastasis from pancreatic cancer
Characteristics of existing medicines, etc.	Although the basic drug siRNA has a definite inhibitory effect as its basic effect, its clinical effect in systemic administration has been poor.
Improved points and effects of modules	Nucleic acid drugs using RNA interference are expected to be the next cancer treatment drugs next to molecular-targeted cancer drugs and cancer immunotherapeutic drugs. The nucleic acid drug DFP-10825 is designed to be effective by intraperitoneal rather than systemic administration, as it specifically inhibits the factors that significantly affect cancer growth by RNA interference. In patients with ovarian cancer or stomach cancer, fluid retention such as pleural fluid and ascites (peritoneal metastasis) is observed at the terminal stage, but ascites is controlled by injecting the drug directly into the abdominal cavity to exert an effect. It is expected to relieve the pain and lead to the patients' prolonging life.
Countries where patents were acquired (May. 2020)	Japan, the U.S., EU, China, Korea, Russia, Republic of China, Hong Kong

(State of development, and future commercialization)
The company has already completed efficacy and pharmacokinetics tests against peritoneal metastasis that causes ascites associated with ovarian, stomach or pancreatic cancer. Preliminary investigations based on the current Good Manufacturing Practice (cGMP) standards have also been completed for the manufacture of study drugs, such as drug substances, DDS and preparations. From now on, after adding preclinical tests according to the Good Laboratory Practice (GLP) standards for conducting non-clinical tests concerning safety of drugs using a part of the funds obtained from the stock listing, the company is planning to apply for IND to the US FDA and will begin the clinical phase I test for patients with peritoneal metastasis of ovarian, stomach or pancreatic cancer in the U.S. It has also received each country's certificates of patent that is pending.
While preparing active pharmaceutical ingredients and test drugs, they will conduct pre-clinical testing and aim to start clinical testing in Japan or the U.S. by FY 2020.

6)「DFP-17729」

Item	Outline
Main target disease	Terminal stage pancreatic cancer, malignant gastric lymphoma, gastric cancer, and lung cancer.
Characteristics of existing medicines, etc.	Urinary alkalinizing agents, which are existing drugs, are targeted for hyperuricemia and others, but it has been confirmed that they provide a life-prolonging effect in pancreatic cancer and have an antitumor effect on each cancer tumor.
Improved points and effects of modules	Normal cells are more alkaline outside the cells than inside the cells, but cancer cells are more acidic outside the cells. This is because the growth of cancer cells promotes glycolysis, producing lactic acid and hydrogen ions, and they are actively released into the extracellular space. DFP-17729 suppresses the growth of cancer by alkalizing the outside of cancer cells. It has been confirmed in animal experiments that the combined use of an anticancer drug and an immune checkpoint inhibitor enhances the effect as compared with the monotherapy with an immune checkpoint inhibitor.
Countries where patents were acquired (as of the end of May. 2020)	Japan, Korea

◎Confirming the clinical efficacy of DFP-17729



(Taken from the reference material of the company)

(State of development, and future commercialization)

The company is preparing for the additional indication of urine alkalizing agents, which are approved and sold as pharmaceutical products, as anti-cancer drugs in Japan.

Because urine alkalizing agents are already being used in clinical practice for the efficacy and effect of "acidosis improvement" to treat "hyperuricemia" and "tumor lysis syndrome," preclinical testing is not necessary.

The company aims to expand the range of anti-tumor effects of existing drugs through the combined use of anti-cancer agents and an immune checkpoint inhibitor and provide new cancer treatments. It also aims to start clinical tests in Japan by FY 2020.

In March 2020, the company signed a licensing contract with Nippon Chemiphar Co., Ltd., by which it agreed to give Nippon Chemiphar Co., Ltd. the exclusive rights to market DFP-17729 in Japan as well as the exclusive rights to manufacture it in order to sell it domestically. Delta Fly Pharma will perform clinical tests of the combined use with existing anti-cancer agents for pancreatic cancer patients, while Nippon Chemiphar Co., Ltd. will be responsible for manufacturing and selling DFP-17729 in Japan after the manufacturing approval is obtained.

In May 2020, the company published a paper about DFP-17729 in the journal of American Association for Cancer Research "Molecular Cancer Therapeutics."

Generally, the 5-year survival rate of pancreatic cancer patients is less than 10%, which is severely low. However, this research indicates that it does not only increase the efficacy of existing pancreatic cancer treatments, but also increase the effectiveness of an immune checkpoint inhibitor (anti-PD-1 antibody). Moreover, DFP-17729 does not show any of the side effects of the existing anti-cancer drugs and it was confirmed that it does not produce extra toxicity from combining it with existing anti-cancer drugs.

1-5 Four characteristics as a bio-venture

The company as a bio-venture has the following four main characteristics.

1) Module drug development

As described above, the company is patenting existing drugs, etc. by re-inventing them with ingenuity based on "modules" (components) and creating new drugs with improved balance between clinical efficacy and safety.

2) Specialized in the development of anti-cancer drugs

By working specifically on "anti-cancer drugs," which still have limited effectiveness and cause various side effects, the company is accelerating the development of new drugs through module drug development and contributing to the improvement of the social life of cancer patients.

3) Development by experienced members

The development members consisting of people who have been engaged in research and development of anti-cancer drugs for many years at pharmaceutical companies and clinicians who are familiar with cancer patients advance the development of drugs with certainty and meet unmet medical needs. This sharply differentiates the company from others, giving competitive advantage.

4) Effective utilization of external resources

The company operates efficiently by focusing on management and operation of research and development without having factories or research institutes and proactively cooperating with external contractors and other organizations for outsourcing tasks.

2. Earnings Trends

2-1 Fiscal Year ended March 2020 Earnings Results

1) Earnings trends

	FY 3/19	FY 3/20	YoY	Difference from the forecast
Operating Revenue	-	100	+100	+100
Operating Cost	592	1,645	+1,053	+579
R&D Expense	376	1,397	+1,020	+575
Other SG&A expenses	215	248	+32	+4
Operating Income	-592	-1,545	-953	-479
Ordinary Income	-671	-1,552	-881	-486
Net Income	-673	-1,555	-882	-486

Unit: Million yen

(Operating Revenue)

The company posted revenues from lump-sum contract payment of the licensing contract with Nippon Chemiphar Co., Ltd.

（Operating Cost）

R&D expenses increased due to the increase of medical institutions for clinical tests of drug pipelines and the number of registered cases, and the progress of manufacturing active pharmaceutical ingredients for the study drugs in the next test.

（Operating income）

Operating loss was 1,545 million yen, up 953 million yen year-on-year.

2) Financial Conditions and Cash Flows

◎Main BS

	End of Mar. 2019	End of Mar. 2020		End of Mar. 2019	End of Mar. 2020
Current Assets	3,532	2,115	Total Liabilities	63	105
Cash	3,508	1,943	Total Net Assets	3,504	2,056
Noncurrent Assets	35	46	Retained Earnings	-2,066	-3,622
Property, Plant and Equipment	31	43	Total Liabilities, Net Assets	3,567	2,162
Total Assets	3,567	2,162	Balance of Short and Long-Term Debts	13	5

Unit: Million yen

Equity ratio was 95.1%, 3.1 points down year-on-year.

◎Cash Flows

	FY 3/19	FY 3/20	Increase/Decrease
Operating cash flow	-585	-1,649	-1,063
Investing cash flow	-3	-13	-9
Free cash flow	-588	-1,662	-1,073
Financing cash flow	3,316	99	-3,216
Cash and Equivalents at the end of term	3,508	1,943	-1,564

Unit: Million yen

The cash position declined.

2-2 Fiscal Year ending March 2021 Earnings Forecasts

	FY 3/20	FY 3/21 (Estimate)	YoY
Operating Revenue	100	300	+200
SG&A	1,645	1,150	-495
R&D Expenses	1,397	880	-517
Other SG&A (R&D Expenses are excluded)	248	270	+22
Operating income	-1,545	-850	+695
Ordinary income	-1,552	-850	+702
Net loss	-1,555	-850	+705

Unit: Million yen

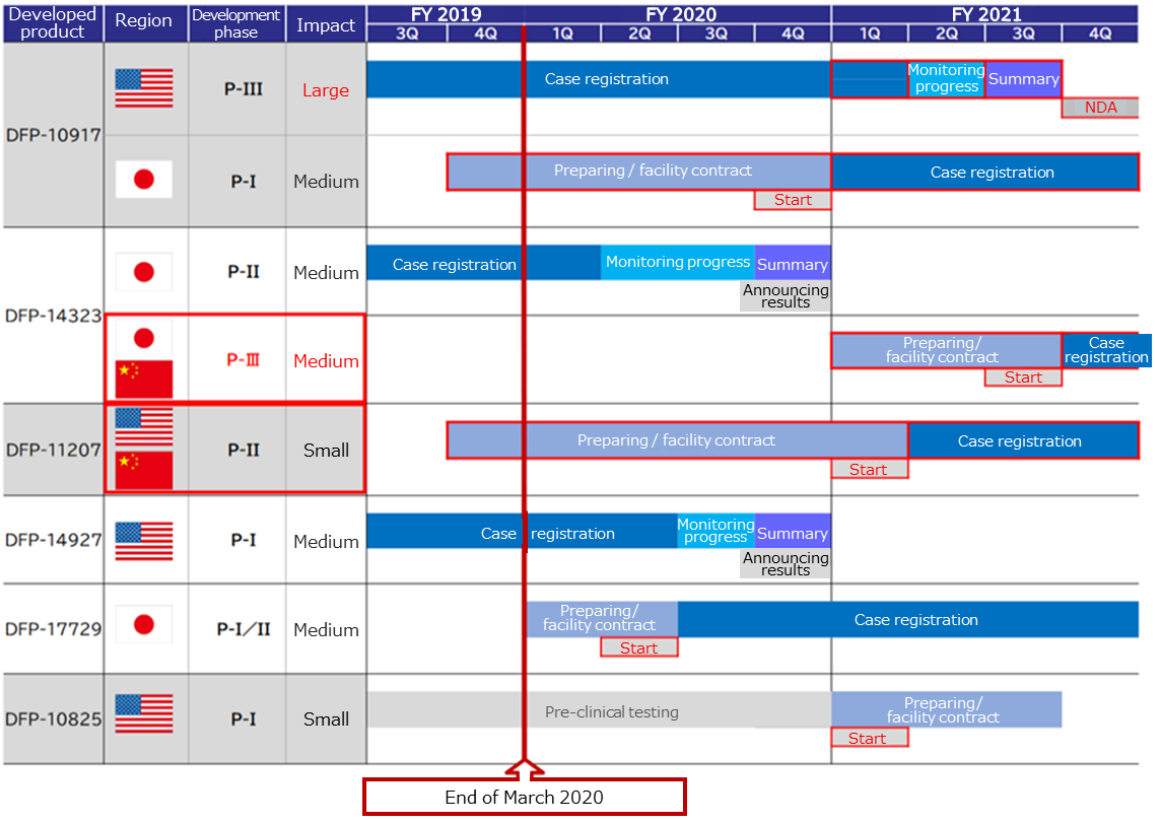
(Operating Revenue)
The company expects to make 300 million yen of milestone compensation for licensing contracts.

As for business revenue, considering the uncertainties of the progress of clinical tests and license negotiations, they thought that posting milestone compensation and lump-sum contract payment to be expected would not be appropriate at this stage. They plan to clarify the outlook when revenue is secured.

(Operating Cost)
The company expects to finish the clinical phase I test of DFP-14927 while further increasing case registration of DFP-10917 clinical phase III test in the U.S. Further, as the case registration of domestic DFP-14323 clinical phase II test was finalized, the company plans to make preparations, making the next clinical phase III test (large-scale controlled trial) jointly with China's pharmaceutical companies. In addition, regarding DFP-17729, for which the company has a partnership with Nippon Chemiphar Co., Ltd., it plans to start domestic clinical tests and will proceed with the development of these drug pipelines. As the company had manufactured active pharmaceutical ingredients and preparations in the previous term earlier than planned, it expects R&D expenses to decrease.

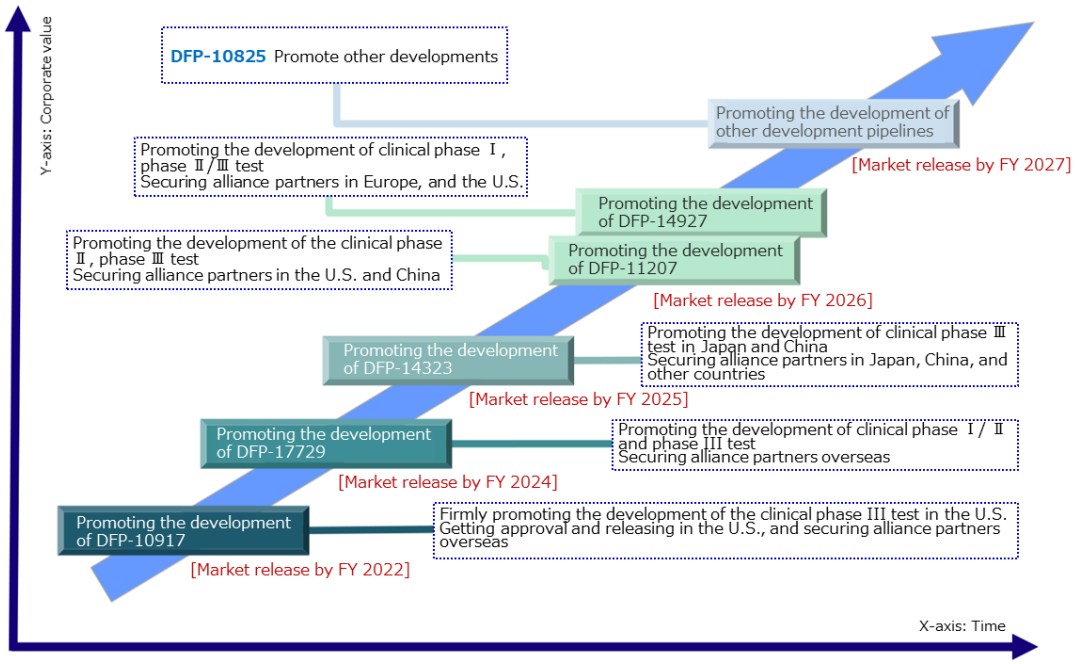
3. Growth Strategy

The main scheduled events for each pipeline from this term through the next term are as below:



(Taken from the reference material of the company)

The company will firmly continue the development of the 4 products undergoing clinical tests and the 2 products undergoing preparation for clinical tests, and from FY 2022, it aims to steadily release them to the market. Further, the company plans to expand profitability and focus on securing alliance partners in Japan, China, Europe, and the U.S.



(Taken from the reference material of the company)

4. Conclusions

For DFP-10917, whose development is making the most progress among the company's pipelines, the company is increasing patients' registrations for its clinical phase III test and the number of facilities that conduct clinical trials in the U.S.Clinical tests were affected by the spread of the new coronavirus in some medical institutions, however, clinical tests in medical institutions located in less-affected regions were continued and there are apparently no major delays at the moment.
Moreover, the company is making steady progress with the development and commercialization of each pipeline. As for DFP-17729, which is expected to be released in the market soon, the company formed a licensing contract with Nippon Chemiphar Co., Ltd. and started preparing for domestic clinical tests.
We will continue to pay attention to each release.

<Reference: Regarding Corporate Governance>

◎Organization type, and the composition of directors and auditors

Organization type	Company with audit and supervisory board
Directors	7 directors, including 4 outside ones
Auditors	3 auditors, including 2 outside ones

◎Corporate Governance Report
The latest update: June 28, 2019.

<Basic policy>
Our company thinks that our mission is to operate our business while putting importance on the benefits of all stakeholders, including shareholders, clients, business partners, employees, and local communities, under the mission of "To provide treatment methods recommendable to cancer patients among relatives with peace of mind through module drug development." To accomplish this, it is indispensable to develop our business stably and perpetually. Our basic policy for corporate governance is to improve systems for securing the soundness, transparency, and efficiency of business administration, which will become the base for the above-mentioned development.

＜Reasons for Non-compliance with the Principles of the Corporate Governance Code＞
It is written that "We follow all of the basic principles."