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/en/

Stock Information

Share Price	Shares Outstanding		Total Market Cap	ROE(Actual)	Trading Unit
¥1,548	5,419,600 shares		¥8,389million	-41.7%	100 shares
DPS(Estimate)	Dividend Yield (Estimate)	EPS(Estimate)	PER(Estimate)	BPS(Actual)	PBR(Actual)
¥0.00	-	¥-239.87	-	¥390.87	4.0times

*Share price is the closing price on December 9. Share Outstanding, DPS, and EPS were taken from the financial results for the second quarter of FY 3/22. ROE and BPS are actual results from the previous fiscal year.

Earnings Trends

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
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 (Actual)	300	-852	-859	-862	-187.34	0.00
Mar. 2022 (Estimate)	100	-1,300	-1,300	-1,300	-239.87	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 is adjusted retroactively.

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

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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 with fewer side effects, 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 reduction of side effects and costs, 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 studies, and for the other 2 candidate drugs are being prepared for the clinical studies.**

- **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.**

- **Operating revenue in the second quarter of the fiscal year ending March 2022 was 100 million yen. The company received milestone income through the licensing agreements with Nippon Chemiphar Co., Ltd. Operating cost was 654 million yen, up 16.1% year on year. The company increased the number of medical institutions and cases in the clinical trials of the development pipeline, and proceeded with the production of active pharmaceutical ingredients and formulations of therapeutic drugs for the next studies. Operating loss increased 90 million yen year on year to 554 million yen.**

- **Operating revenue for the term ending March 2022 as milestone compensation for licensing agreements is estimated at 100 million yen, down 200 million yen year on year. In addition to revenue from milestone compensation for DFP-10917, the company is expected to earn revenue, such as upfront payment through alliances with new partners, as the clinical studies of several candidate compounds for anticancer drugs, including DFP-10917 which is undergoing the clinical phase III study in the U.S. and DFP-14323 which is going through the clinical phase II study in Japan. The company plans to announce its future outlook in a timely manner when revenue is finalized. Operating cost is projected to grow 250 million yen year on year to 1.4 billion yen. R&D expense is expected to rise 223 million yen year on year so that the company can make steady progress with each of the pipelines under development. Operating loss will stand at 1.3 billion yen, up 447 million yen year on year.**

- **We are looking forward to the company's steady progress toward the new drug application of DFP-10917 in the first half of the term ending March 2023 and its launch in the second half of the same term. The company aims to submit new drug application for DFP-10917 at the earliest time, and this is considered as a concrete example of the successes of the company, which was founded 11 years ago.**

1. Company Overview

Delta-Fly Pharma upholds the corporate ethos: "To provide treatment methods recommendable for cancer patients and their families with peace of mind, by diagnosing all states of cancer patients rather than focusing on 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 with fewer side effects, 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 with fewer side effects and friendly to patients through module drug development. As of September 2020, 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.

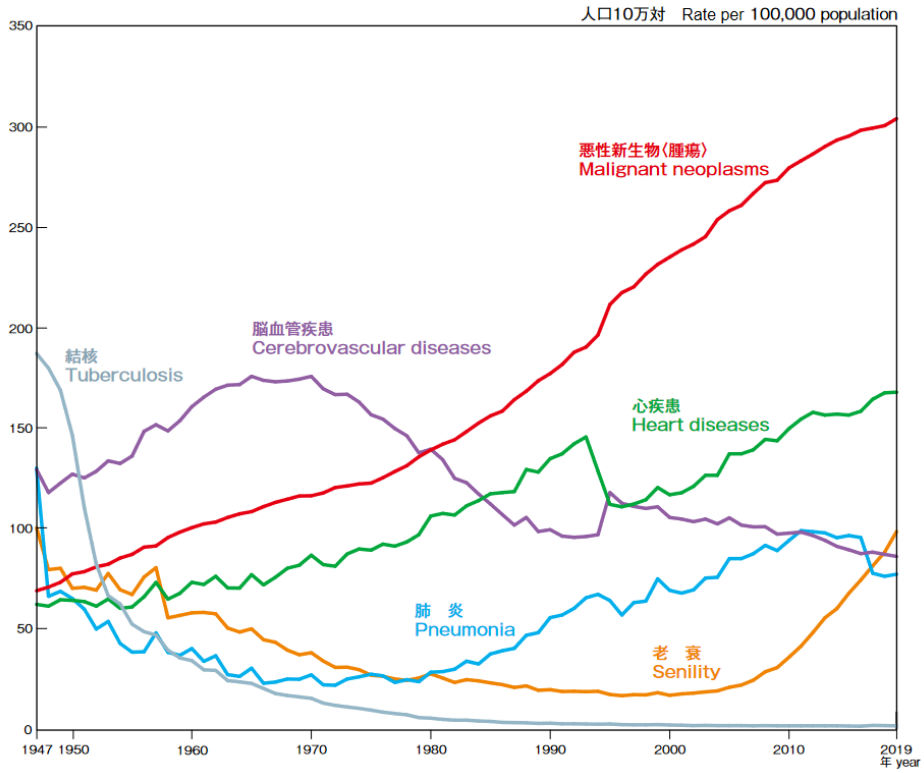
Corporate ethos	To provide treatment methods recommendable for cancer patients and their families with peace of mind, by diagnosing all states of cancer patients rather than focusing on only cancer,

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

1-3-1 The number of cancer death cases continues to increase

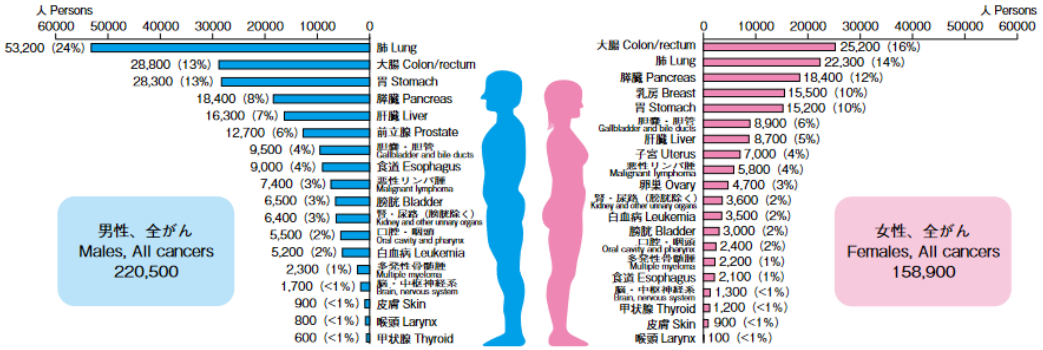
According to the Foundation for Promotion of Cancer Research's "Cancer Statistics 2021," cancer (malignant neoplasm) has been the leading cause of death since 1981, with 376,425 deaths in 2019 and a mortality rate of 304.2 deaths in a population of 100,000, accounting for 27.3% of total deaths.
It is said that the incidence of cancer is growing due to the aging of the population, the change in lifestyles, including dietary habits, etc.



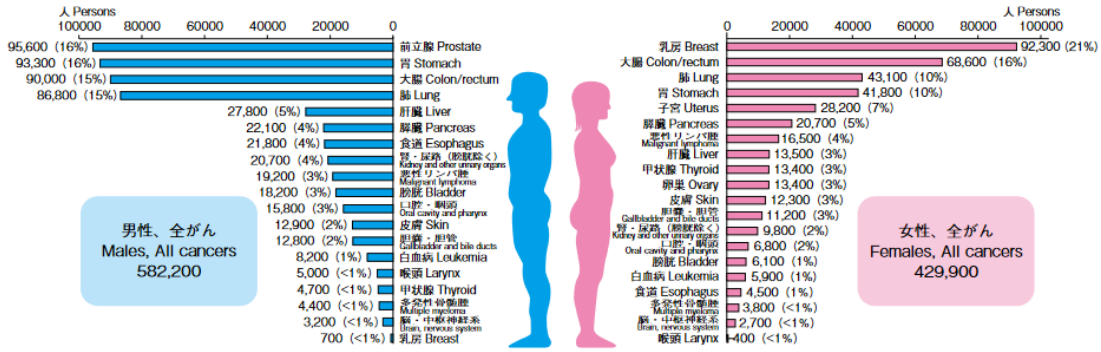
(Taken from the reference material of the company)

The estimated number of cancer deaths in Japan in 2020 was approximately 379,400 (220,500 men and 158,900 women). Lung cancer accounted for the largest percentage (24%) of all cancer deaths among males, followed by colorectal cancer (13%), gastric cancer (13%), pancreatic cancer (8%), and liver cancer (7%). Among females, colorectal cancer accounted for the most significant percentage (16%) of all cancer deaths, followed by the lung cancer (14%), pancreas (12%), breast (10%), and stomach (10%).
The estimated number of cancer cases in Japan in 2020 was approximately 1,012,000 (582,200 for men and 429,900 for women). Prostate cancer accounted for 16% of all male patients, followed by gastric cancer (16%), colorectal cancer (15%), lung cancer (15%), and liver cancer (5%). Breast cancer accounted for 21% of all female cases, followed by colorectal cancer (16%), lung cancer (10%), gastric cancer (10%), and uterine cancer (7%).

(1) 部位別予測がん死亡数（2020年）
Projected Number of Cancer Deaths by Site (2020)



(2) 部位別予測がん罹患数（2020年）
Projected Number of Cancer Incidence by Site (2020)



(Taken from the reference material of the company)

1-3-2 Cancer treatment methods

The main treatment methods for cancer are surgical therapy, radiotherapy, and chemotherapy (anticancer drug treatment). Chemotherapy (anticancer drug treatment) is the third treatment that is administered after surgery and radiation.
The anticancer drug is generally administered as the standard treatment, which is the most recommended treatment as large clinical trials have shown potential therapeutic efficacy and proved it safe, in patients with stage 3-4 cancer.

1-3-3 Anticancer drug development and its side effects

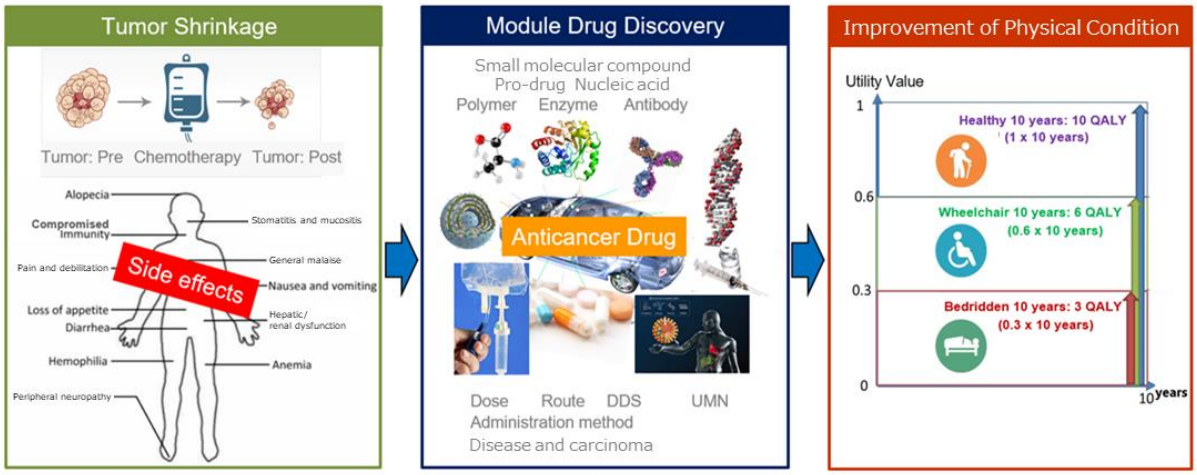
European, American, and Japanese companies are developing various anticancer drugs in response to the increase in cancer patients worldwide. However, as is well known, the various side effects associated with anticancer drug treatment are a significant burden for cancer patients. Therefore, there is a vital need to reduce the side effects to improve patients' QOL (Quality of Life).

(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)

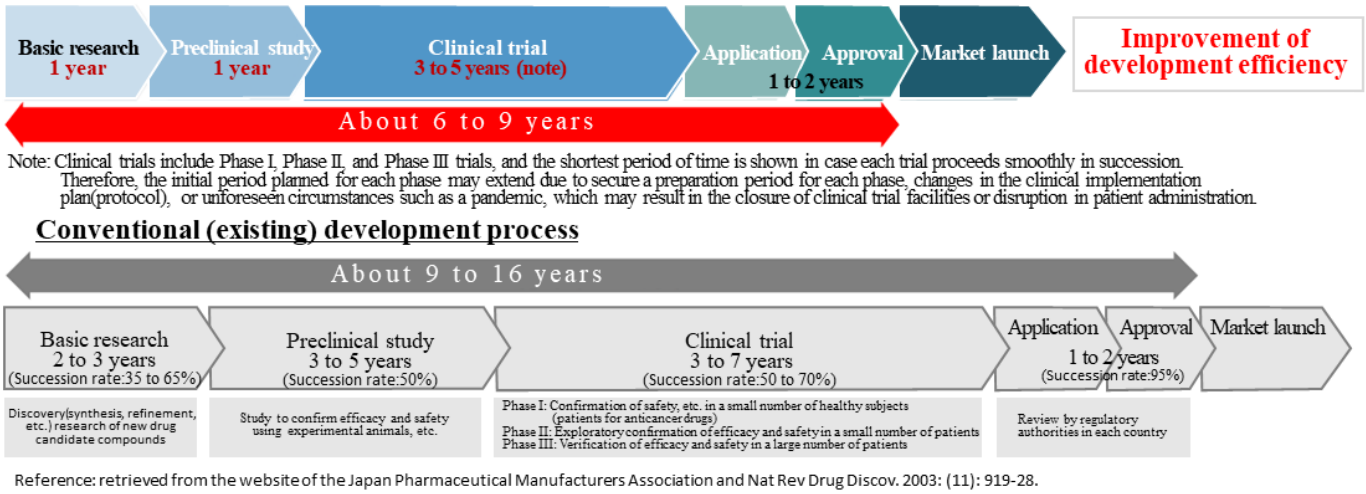
Module Drug Development is the development method of new anticancer drugs that have an improved balance between clinical efficacy and safety by using the existing active substances with the anticancer property as modules (components) and assembling them into novel anticancer drugs with ingenuity (dosage and administration, combination methods, etc.).
Through "module drug development," the company focuses on not only "cancer circumstances" but also the whole conditions of "cancer patients," improves the anticancer drugs with fewer side effects-and which have various side effects in a multifaceted manner, and produces medicines whose side effects are so fewer that you can recommend them to cancer patients and their families.

(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 reduce. ・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.

Typically, to develop a single drug, compounds that act on a specific part of the cancer are screened in the basic exploratory research stage, and potential compounds are selected as anticancer drug candidates. The clinical stage reviews the effect of the drug, and it is necessary to demonstrate its efficacy and safety in clinical trials. Thus, it takes a long period of 10 to 15 years from the basic stage for research and development, and large-scale funds amounting to billions to tens of billions of yen are required.
In addition, there is a considerable risk that development will be discontinued due to various factors at each stage leading up to approval. That is why improving the efficiency of the R&D process and reducing development risks have become significant issues for pharmaceutical companies and drug developing venture companies around the world.

In contrast, "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.



(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. 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).

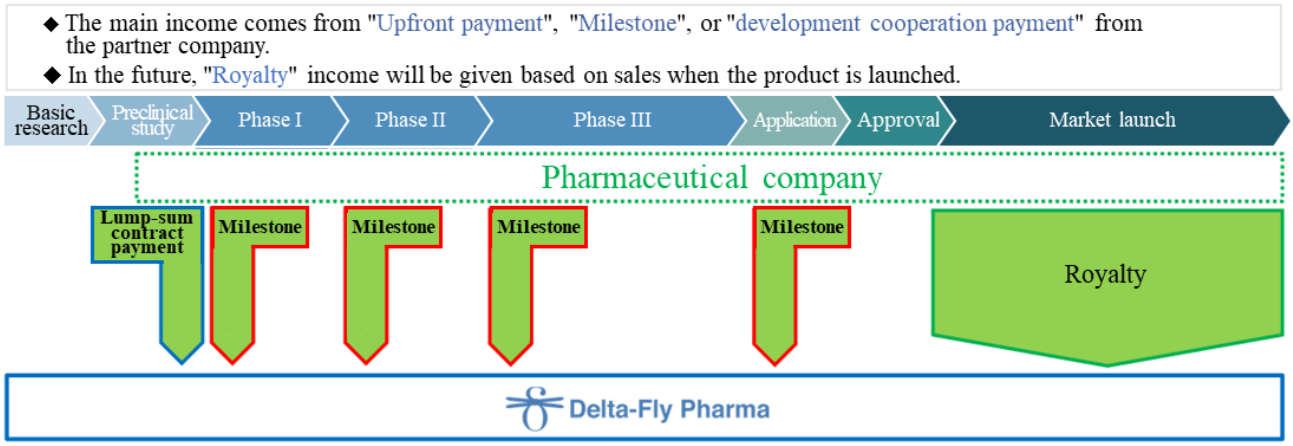
(Revenue model)

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.

Revenue Item	Details
Lump-sum contract payment	Income received as a lump-sum contract payment
Milestone	Income received when achieving preset events, depending on the progress of research and development
Development cooperation expenses	Income that partner companies bear according to R&D costs
royalties	Income received according to revenue after drug sales

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

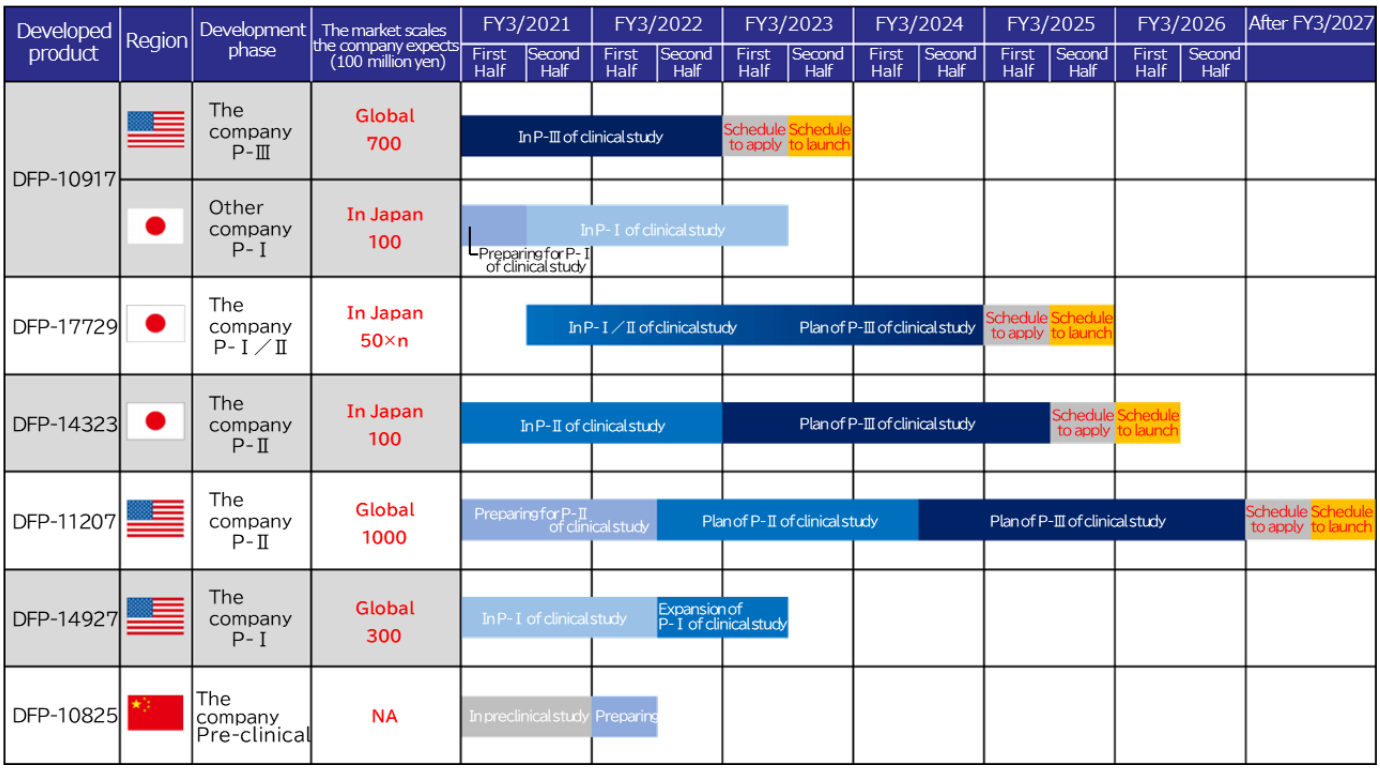
Partner	Contract details	Contract Duration
Nippon Shinyaku Co., Ltd. (1st section of TSE, 4516)	Signed a contract for an exclusive license right for DFP-10917	Until the patent right in Japan expires or 15 years after the start of sales, whichever is later
Nippon Chemiphar Co., Ltd. (1st section of TSE, 4539)	Signed a contract for an exclusive license right for DFP-17729	Until Nippon Chemiphar Co., Ltd. and Sublicensees discontinue sales of this product



(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 studies. For the remaining two candidate drugs, clinical studies 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 during the year associated with acute myeloid leukemia (AML) 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. The product excels in the balance between effectiveness and safety, and is optimal for the treatment of terminal hematologic cancer.
Countries where patents were acquired (May 2021)	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 in complete remission for 48% (14/29) of patients in the phase II, indicating high effectiveness. Taking 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 by US FDA, however, as the treatment guideline of refractory and recurrent acute myeloid leukemia was changed. After the startup meeting with US FDA, the company re-submitted the revised protocol for the clinical Phase III study and the screening of research subjects started.

In consideration of the impact of the new coronavirus infection, the number of hospitals participating in the clinical trial has been increased to 39 in order to promote case registration, and the Phase III clinical trial is underway.

As the company has already secured the active pharmaceutical ingredients and final preparations for the new drug application of DFP-10917, it aims to submit an application in the first half of the term ending March 2023 and launch the product in the second half of the term.

In May 2021, as part of the preparations for new drug application, DFP-19017 was given an international nonproprietary name of Radgocitabine by the committee on International Nonproprietary Names for Pharmaceutical Substances under the World Health Organization (WHO).

Deciding on an international nonproprietary name for a pharmaceutical substance is an important process of new drug approval, and the name so given will be used as a universal proper noun after the substance is approved as a new drug.

In Japan, Nippon Shinyaku Co., Ltd., the licensee, submitted a notification of a clinical study plan to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 8, 2021 in order to initiate the clinical phase I study, and received permission from the PMDA on February 8 to conduct the clinical phase I study in Japan targeting refractory or relapsed AML patients.

Regarding the rights in territories outside Japan, negotiations for licensing contracts with pharmaceutical companies in Europe, the U.S., and China are in progress.

(Patent-related)

The company has applied for a patent globally in major countries for its invention of using DFP-10917 with the new derivative of Venetoclax (VTX) in combination treatment and as combination medication, and decision on granting a patent was made in Japan in June of 2021.

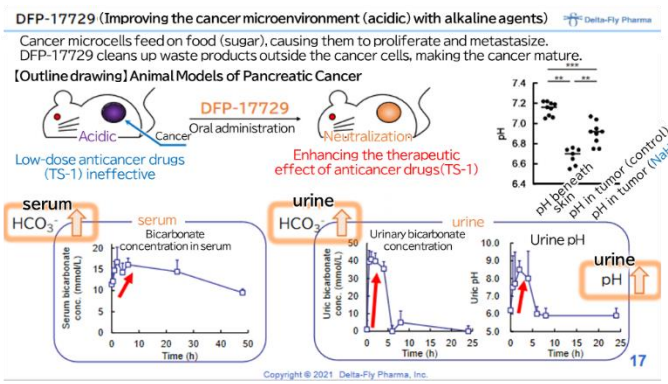
The new derivative of Venetoclax, for which the company submitted a patent, is a new substance acquired by forming a covalent bond between Venetoclax and a water-soluble polymer, and can selectively transport the active substance of Venetoclax to the targeted cancer cells; in experiments on animals transplanted 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.

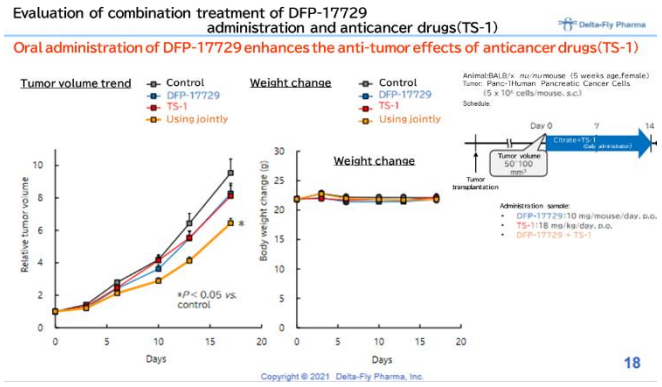
The company intends to carry out clinical studies on combination treatment using DFP-10917 in combination with VTX with the aim of maximizing the markets and prolonging the exclusive marketing period in major countries following manufacturing and sale approval in the U.S. for use of DFP-10917 alone as slated for the term ending March 2023.

2)「DFP-17729」

Item	Outline
Main target disease	Terminal stage pancreatic cancer, malignant gastric lymphoma, gastric cancer, and lung cancer. The annual death toll from pancreatic cancer is about 470,000 worldwide and about 37,000 in Japan.
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. In other words, it cleans the area surrounding the cancer, and calms the cancer down. 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 (May 2021)	Japan, Korea, Republic of China

◎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 practices for the efficacy and effect of "acidosis improvement" to treat "hyperuricemia" and "tumor lysis syndrome," so the preclinical study 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.

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 marketing right and the exclusive manufacturing right of DFP-17729 in Japan.
Delta-Fly Pharma will perform clinical studies 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 PMDA approval.

In May 2020, the company submitted a paper about DFP-17729 and it's accepted by 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.

After obtaining these results, the company submitted a clinical trial plan to the PMDA in July 2020 with the aim of executing the clinical phase I/II studies in multiple medical institutions in Japan, targeting patients with terminal pancreatic cancer, and received permission for the execution of the studies after completion of an examination by PMDA.
Taking the condition of the terminal pancreatic cancer patients into account, the clinical study will be used to investigate and confirm the safety/effectiveness of the clinical phase I/II studies before transitioning into the clinical phase III study. The clinical phase I study will confirm the safety when using the existing drugs and DFP-17729 at the same time, and the clinical phase II study will be a comparative test to confirm whether DFP-17729 excels compared to existing drugs.

The clinical phase I study had been carried out since patients' enrollment for the study began on November 18, 2020 at three major hospitals in the Kanto region. Following completion of the period of evaluating the safety for all of the patients enrolled in the study, the safety of DFP-17729 when used in combination with anticancer drugs was confirmed through deliberations on April 15, 2021 by the safety evaluation committee, and the company was permitted to move on to the clinical phase II study.
In the clinical phase II study in which six major hospitals participate, the drug was administered to the first patient on April 22, 2021.
As this study is performed as clinical phase I/II studies, the company made an almost seamless transition from the safety confirmation by the safety evaluation committee in the clinical phase I study to the start of administration of the drug in the clinical phase II study.
After that, patients' enrollment was completed on November 11, 2021. Over the following six months, the company will verify the usability of DFP-17729. Depending on the results, the company will decide whether it will be possible to get approval for new drug application to the Pharmaceuticals and Medical Devices Agency (PMDA) or prepare for Phase III clinical trials.

Meanwhile, in January 2021, the company announced that it was confirmed, using animals to which human pancreatic cancer cells were transplanted, that DFP-17729, an agent for improving the cancer microenvironment, boosts the therapeutic effect of TS-1 which is a drug against pancreatic cancer. The company believes that this discovery has provided firm foundations for development technology and intellectual property in Japan for taking indications for not only pancreatic cancer but also for other cancers, such as malignant melanoma, gastric cancer, and non-small cell lung cancer.

After proceeding with the clinical study in Japan in collaboration with the company's partner, Nippon Chemiphar Co., Ltd., the company plans to expand into Europe, the U.S., and various Asian countries in the future, based on the clinical study data obtained in Japan.

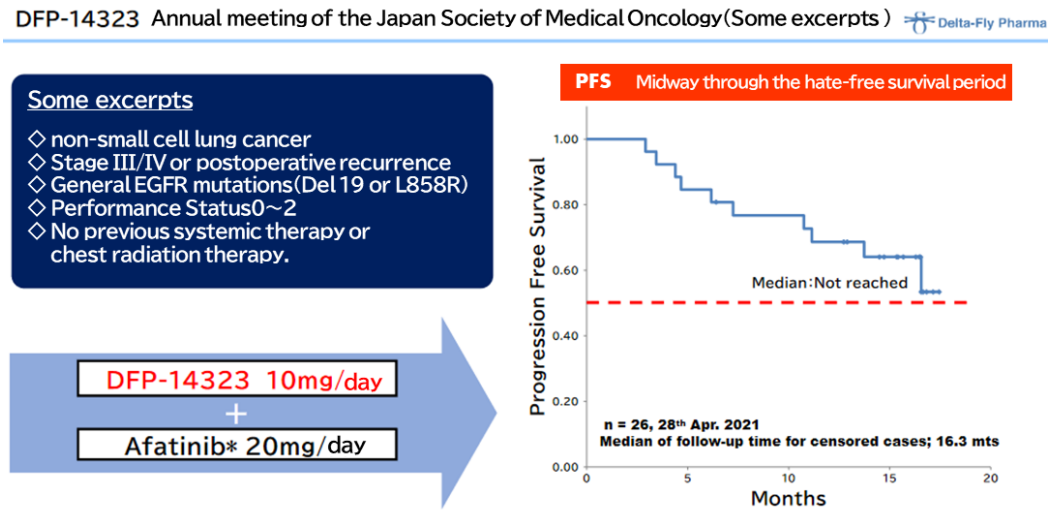
At present, the schedule is to start the Phase III clinical trial during the term ending March 2023, submit the new drug application during the first half of the term ending March 2025, and launch the product during the second half of the same term.

3)「DFP-14323」

Item	Outline
Main target disease	Terminal stage lung cancer, etc. The annual death toll from lung cancer is approximately 1.8 million worldwide and about 75,000 in Japan.
Characteristics of existing medicines, etc.	The existing medicine "Ubenimex" (UBX) 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 immune function in cancer patients is improved, and the effectiveness of existing drugs is enhanced. The drug is expected to treat terminal or elderly patients of solid tumors.
Countries where patents were acquired (May 2021)	Japan, the U.S., EU, Australia, Korea, Russia, Republic of China

◎The clinical efficacy of DFP-14323



※ The standard volume of Afatinib is 40mg per day, and we administered half of that volume at this time.

(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 study for the combination therapy 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 the clinical studies have increased in Japan, the company proceeded with registering the new patients' enrollment. In March 2020, the registration was complete for all patients' enrollment.

DFP-14323 is the development code for obtaining approval as a Ubenimex's new drug with expanded new indications.

Afterwards, during the effect measurement of the clinical phase II study based on the disease control rates (DCR) of all registered cases (including brain metastasis cases), a DCR of 100% was confirmed in June 2020, and efficacy was confirmed with the DCR of 100% and an overall response rate (ORR) of 65.4% or higher, in an effect measurement evaluation by independent medical doctors. The company thinks the product displayed excellent curative effects for brain metastases in patients of non-small cell lung cancer.

Further, based on the fact that it was discovered to be useful as a combination medicine for the treatment of patients of terminal non-small cell lung cancer with brain metastasis, the company made an international patent application to the member nations of the Patent Cooperation Treaty (PCT).

In addition, the results of the clinical phase II study conducted in Japan were presented in a poster presentation at European Society for Medical Oncology (ESMO) ASIA CONGRESS 2020 held in November 2020, showing the latest data on great safety and progression-free survival (PFS) confirmed in the study.

The data on PFS is important information for determining a protocol of the clinical phase III study, and the company plans to accelerate the clinical phase III study, which is scheduled to be started in the term ending March 2023, in cooperation with Japanese and overseas pharmaceutical companies that are highly interested in the clinical study data of the clinical phase II study.

Based on the favorable results of the clinical phase II study held in Japan as well as its intellectual property foundation, the subjects for the clinical phase III comparative study for DFP-14323 are scheduled to be Non-small cell lung cancer patients with brain metastasis, and by including China, which is said to have the largest number of lung cancer patients in the world, the company is proceeding with preparations to obtain approval and release DFP-14323 as soon as possible.
At present, the schedule is to start the Phase III clinical trial in the term ending March 2023, submit the new drug application in the second half of the term ending March 2025, and launch the product during the first half of the term ending March 2026.

The company signed a contract for an exclusive license right in Japan with Kyowa Chemical Industry Co., Ltd. (unlisted), but in November 2020, Kyowa Chemical Industry Co., Ltd. withdrew its plan for joint development and terminated the contract because of internal circumstances at Kyowa Chemical Industry.
The company will continue pursuing the manufacture and sales approval of the generic drugs of Ubenimex from PMDA on their own. Furthermore, the company will wait till around June 2021, for the evaluation of Progression Free Survival (PFS) and Overall Survival (OS), and apply to the PMDA for the manufacture and sales approval for the additional indication product for Ubenimex.

(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.

4)「DFP-11207」

Item	Outline
Main target disease	Solid tumors (such as pancreatic cancer) The annual death toll from pancreatic cancer is about 470,000 worldwide and about 37,000 in Japan.
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. Optimal for preventing post-operation relapse or metastasis of micro cancer, and high life-prolongation effect can be expected.
Countries where patents were acquired (May 2021)	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 study for solid tumors (digestive system cancer), and determined 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 the clinical phase II study with the combined use of anticancer drugs.

The company announced the results of the clinical phase I study and the food effects' study at the conferences of the Chinese Society of Clinical Oncology (CSCO) and Japan Society of Clinical Oncology (JSCO) in 2019.
Moreover, in May 2020, the result of the clinical Phase I study in the US 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.
At present, the schedule is to start the Phase II clinical trial in the second half of the term ending March 2022, start the Phase III clinical trial in the second half of the term ending March 2024, and submit the new drug application and launch the product after the term ending March 2027.

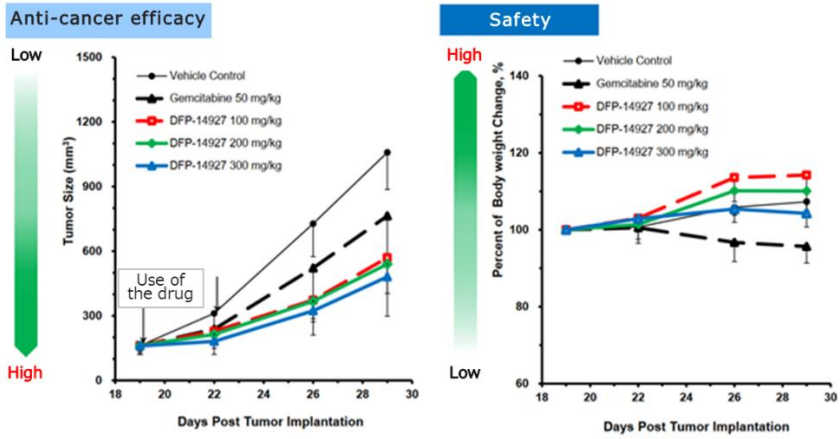
(Patent-related)
The company filed a patent to the member nations of the Patent Cooperation Treaty (PCT) and Taiwan after successful development of the stable preparation as a result of its concentrated efforts to improve the techniques of preparing DFP-11207 that is unstable and sensitive to humidity. In September 2021, the Japan Patent Office granted the patent.

A patent for the stable preparation, if granted, will provide a longer-term foundation for the intellectual property of DFP-11207.

5)「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 2021)	Japan, the U.S., China, Australia, Russia, Hong Kong

◎Confirming DFP-14927 efficacy on animals
In animal models of pancreatic cancer, both the efficacy and safety of DFP-14927 were superior than gemcitabine, the standard chemotherapy for pancreatic cancer.



(Taken from the reference material of the company)

(State of development, and future commercialization)

The preclinical study has been completed in the U.S. The data of the preclinical study indicates 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 study, 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 study in the U.S. And the company started clinical phase I study aimed at patients with digestive system cancer including pancreatic cancer and gastric cancer.

Due to the impact of the spread of the novel coronavirus, the case registration has slowed down in areas with large numbers of infected patients, but once the safety around the present dosage is confirmed, the company plans to select the optimal cancer, add multiple major cancer centers in the U.S., and move on to an extended study equivalent to the clinical phase II study in the second half of the term ending March 2022.

It also plans to discuss the possibility of the clinical phase I/II studies on myelodysplastic syndrome (MDS), which are a type of hematologic cancer.

Regarding distribution rights in territories outside Japan, negotiations for licensing contracts with pharmaceutical companies in Europe, the U.S., and China are in progress.

6)「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 (Nov. 2020)	Japan, the U.S., EU, China, Australia, Korea, Russia, Republic of China, Hong Kong

(State of development, and future commercialization)

The company has already completed efficacy and pharmacokinetics studies 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 the clinical study drugs, such as drug substances, DDS and preparations. From now on, after adding preclinical studies according to the Good Laboratory Practice (GLP) standards for conducting non-clinical studies 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 study for peritoneal metastasis of ovarian, stomach or pancreatic cancer patients in the U.S. The company has already received each country's patent certifications.

The company began preparations for clinical studies in the first half of the term ending March 2022 as it is currently performing a preclinical study using animals as well as preparing active pharmaceutical ingredients and investigational products.

1-5 Characteristics and advantages as a bio-venture

The company, a bio-venture company, has the following features and advantages.

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) Advantage in cancer treatment drugs

The company is developing drugs focusing on patients with relapsed or refractory cancer after receiving standard therapy. Therefore, the company is developing drugs to provide an anticancer drug for patients in which standard treatments were ineffective and cannot find a treatment drug after that. If the developed product is launched in the future, it will have an advantage as a therapeutic drug after standard therapy.

4) 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.

5) 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 Second quarter of Fiscal Year ending March 2022 Earnings Results

1) Earnings trends

	2Q of FY 3/21	2Q of FY 3/22	YoY
Operating Revenue	100	100	0
Operating Cost	563	654	+90
R&D Expense	422	477	+54
Other SG&A expenses	140	177	+36
Operating Income	-463	-554	-90
Ordinary Income	-463	-555	-92
Net Income	-464	-557	-92

Unit: Million yen

(Operating Revenue)

The company earned milestone income through the licensing agreements with Nippon Chemiphar Co., Ltd.

(Operating Cost)

The number of medical institutions undertaking the clinical studies for pipelines under development and the number of patients' enrollment increased, and progress was made in manufacturing of active pharmaceutical ingredients and preparations as investigational products for next studies.

(Operating income)
Operating loss increased 90-million-yen year on year to 554 million yen.

2) Financial Conditions and Cash Flows

◎Main BS

	End of Mar. 2021	End of Sep. 2021		End of Mar. 2021	End of Sep. 2021
Current Assets	2,115	1,696	Total Liabilities	82	98
Cash	2,088	1,676	Total Net Assets	2,078	1,642
Noncurrent Assets	45	44	Retained Earnings	-4,484	-5,042
Property, Plant and Equipment	41	40	Total Liabilities, Net Assets	2,161	1,741
Total Assets	2,161	1,741	Balance of Short and Long-Term Debts	-	-

Unit: Million yen

Total assets decreased by 420 million yen from the end of the previous fiscal year to 1,741 million yen due to a decrease in cash and deposits.
Net assets decreased by 435 million yen to 1,642 million yen due to an increase in capital stock and capital reserve from the exercise of stock acquisition rights, while retained earnings decreased by 557 million yen.
The equity ratio decreased by 1.8 points from the end of the previous fiscal year to 94.3%.

2-2 Fiscal Year ending March 2022 Earnings Forecasts

	FY 3/21	FY 3/22 (Estimate)	YoY
Operating Revenue	300	100	-200
Operating Cost	1,152	1,400	+247
R&D Expenses	866	1,090	+223
Other SG&A Expenses	285	310	+24
Operating loss	-852	-1,300	-447
Ordinary loss	-859	-1,300	-440
Net loss	-862	-1,300	-437

Unit: Million yen

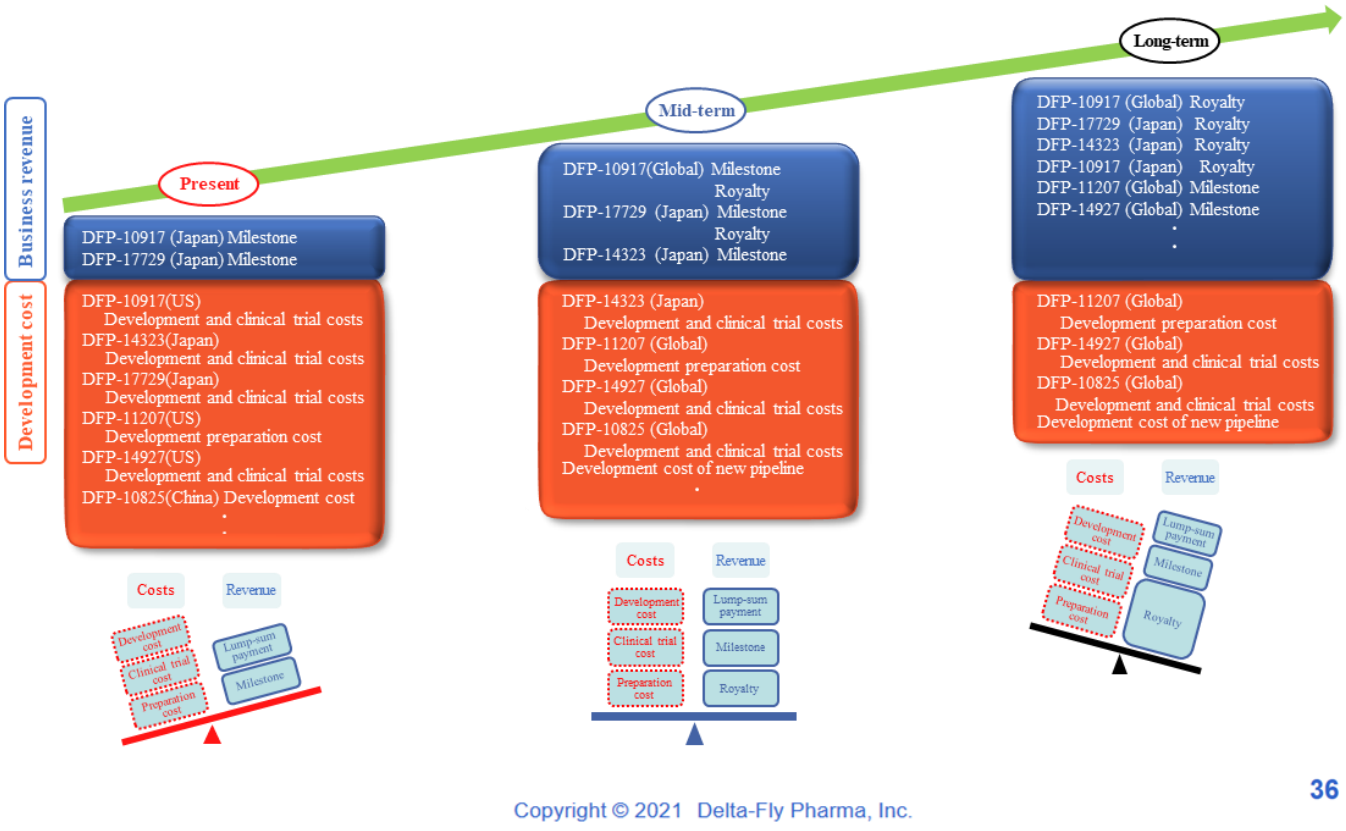
(Operating Revenue)
Operating revenue as milestone compensation for licensing agreements is estimated at 100 million yen, down 200 million yen year on year.
In addition to revenue from milestone compensation for DFP-10917, the company is expected to earn revenue, such as lump-sum contract payments through alliances with new partners, as the clinical studies of several candidate compounds for anticancer drugs, including DFP-10917 which is undergoing the clinical phase III study in the U.S. and DFP-14323 which is going through the clinical phase II study in Japan.
The company plans to announce its future outlook in a timely manner when revenue is finalized.

(Operating Cost)
Operating cost is projected to grow 250 million yen year on year to 1.4 billion yen.
The company will continue patients' enrollment for the Phase III clinical trials of DFP-10917 in the United States, complete the Phase I clinical trials for DFP-14927 in the United States, and proceed to expansion trials. In addition, with the completion of patients' enrollment in Japan for the Phase II clinical trials of DFP-14323, the company is preparing for the Phase III clinical trial (large-scale comparative study), including joint efforts with domestic and overseas pharmaceutical companies.
The company is scheduled to proceed with the Phase I and II clinical trials in Japan for DFP-17729, which is a collaboration between the company and Nippon Chemiphar Co., Ltd., and register patients' enrollment for the Phase II trials. R&D expenses are expected to increase to advance these development pipelines steadily.

(Operating loss)
Operating loss will stand at 1.3 billion yen, up 447 million yen year on year.

3. Growth Strategy

As for development investments, the company will implement development investments in the world (Europe, the U.S., and Asia) and Japan using on-hand funds, license fees, fund procurement, etc., to increase corporate value.
Currently, the costs are increasing, and the company is recording a loss. However, Delta-Fly Pharma aims to systematically launch drug pipelines, pay close attention to the balance of income and expenditure, and increase profits.



(Taken from the reference material of the company)

The company will firmly continue the development of the 4 products undergoing the clinical studies and the 2 products undergoing preparation for the clinical studies, 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.

4. Conclusions

We are looking forward to the company's steady progress toward the new drug application of DFP-10917 in the first half of the term ending March 2023 and its launch in the second half of the same term. The company aims to submit new drug application for DFP-10917 at the earliest time, and this is considered as a concrete example of the successes of the company, which was founded 11 years ago.

<Reference: Regarding Corporate Governance>

◎Organization type, and the composition of directors and auditors

Organization type	Company with corporate auditors
Directors	8 directors, including 4 outside ones
Auditors	3 auditors, including 2 outside ones

◎Corporate Governance Report

The latest update: June 30, 2021.

<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 for cancer patients and their families 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."