



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 Outstand	ding	Total Market Cap	ROE(Actual)	Trading Unit
¥2,010	4	4,369,600 shares	¥8,782 million	-	100 shares
DPS(Estimate)	Dividend Yield (Estimate)	EPS(Estimate)	PER(Estimate)	BPS(Actual)	PBR(Actual)
¥0.00	-	¥-188.31	-	¥228.15	8.8 times

^{*}Share price is as of closing on April 2. The number of shares outstanding was taken from the brief financial report for the third quarter of the term ending March 2019. BPS is the value as of the end of the previous term.

Earnings Trends

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
Mar. 2015 (Actual)	408	-281	-288	-290	-127.65	0.00
Mar. 2016 (Actual)	145	-584	-595	-597	-185.53	0.00
Mar. 2017 (Actual)	902	328	323	305	88.31	0.00
Mar. 2018 (Actual)	150	-243	-244	-246	-71.20	0.00
Mar. 2019 (Estimate)	200	-682	-739	-741	-188.31	0.00

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

This report introduces the company overview, 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 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 3 candidate drugs are under clinical tests, and for the other 3 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.
- We interviewed the President Eshima. He said, "As our company has just been listed, it is necessary to take a little more time to obtain approval and sell our products, but all of us will join hands to support those who are suffering from cancer. We would appreciate your support from the mid/long-term viewpoint."
- Module drug development could be imitated by other companies, but Delta-Fly Pharma has been solely producing some results, by launching 6 pipelines, out of which 3 drugs are undergoing clinical tests and one of them are going to undergo a final clinical test. This has been realized by their development capability based on the unique ideas and ingenuity of an experienced development team led by the President Eshima. This differentiates the company sharply, giving unwavering competitive advantage. In order to achieve sustainable growth, it is indispensable to further enhance the capability of development. Accordingly, we would like to pay attention to their efforts to strengthen their business base, including the development of organizations, and their progress. On the other hand, they aim to obtain approval for DFP-10917, which has made the most development progress, and release it in the U.S. by fiscal 2022, so it takes some time to commercialize it and earn profits, but we hope that they will proceed swiftly with the development of products, which are socially meaningful as they will improve the quality of life for patients and their family members and reduce social loss.

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 March 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

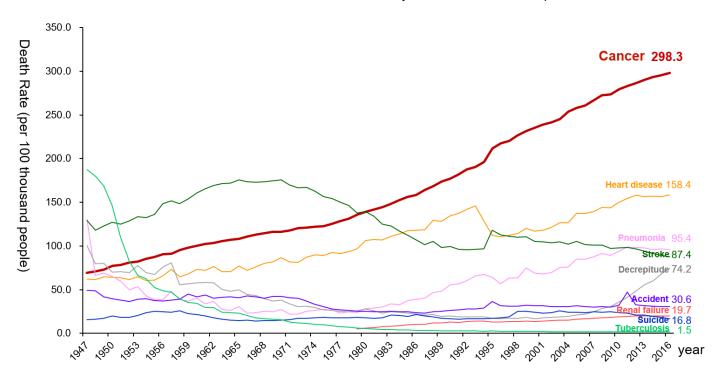
As mentioned later, the company considers that its social mission is not to develop anticancer drugs only for eradicating "cancer," but to provide anticancer treatment with reasonable price while curbing side effects, which are serious issues with anticancer drugs, so that patients and their family members 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, Labour 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.

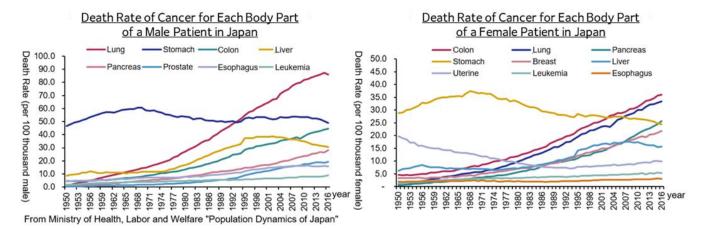
Annual trend of death rate for major cause of death in Japan



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

(Taken from the reference material of the company)





(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.

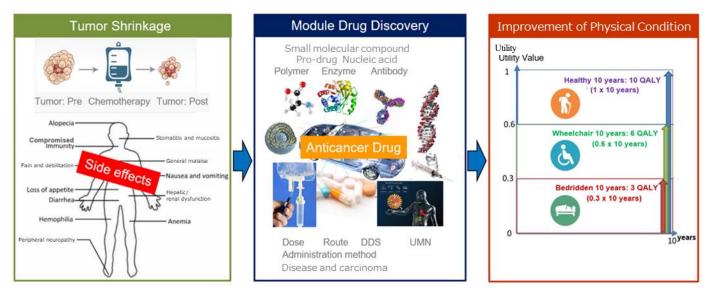
(Mechanism of side effects)

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)

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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.

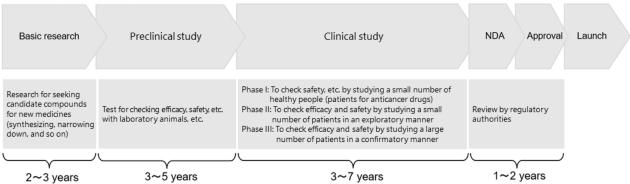
In addition, when focusing on the issues with the treatment of cancer patients, the combination of off-patent pharmaceutical products by utilizing the knowledge and know-how of anticancer drugs enables them to be patented as new anticancer drugs

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.

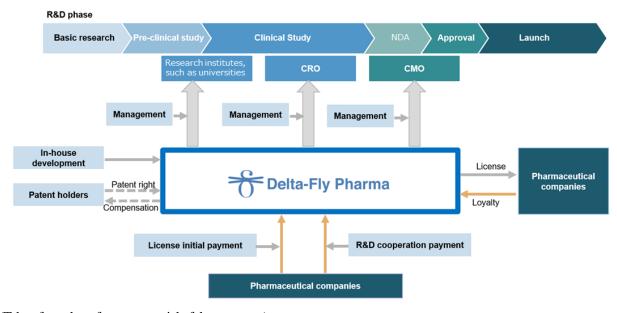
As long as they try to solve the problems with anticancer drugs, they can create totally new anticancer drugs. Therefore, the company is certain that "module drug development" will bring significant innovation to methods for creating medicines.

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).



(Taken from the reference material of the company)

(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 two pharmaceutical companies.

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



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. Three candidate drugs are undergoing clinical tests. For the remaining three candidate drugs, clinical tests are being prepared.

Pinolino	Pipeline Target disease		Pre-clinical Phas	(Clinical Study		NDA	Approval	Launch
Fipelille				Phase I	Phase II	Phase III	NDA	Дррготаг	Laurien
DFP-10917	r/r AML	US	Prepara	ation for Phas	se III				
DFF-10917		Japan	Preparation for Phase I						
DFP-14323	NSCLC etc.	Japan		Ph	ase II				
DFP-11207	Solid tumor (Pancreatic cancer)	US, EU	Preparation fo	r Phase II					
DFP-14927	Solid tumor Hematological cancer	US	Preparation for Phase I						
DFP-10825	Peritoneal metastasis (Gastric or Ovarian cancer)	_	Pre-clinical						
DFP-17729	Solid tumor	Japan		ration linical					

(Taken from the reference material of the company)

1) 「DFP-10917」

Item	Outline
Target disease	Refractory and recurrent acute myeloid leukemia
	(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	The existing medicine CNDAC is targeted at solid tumors. Dosage is high, and
medicines, etc.	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	The dosage was reduced, and administration was conducted intravenously and continuously
of modules	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.

(State of development, and future commercialization)

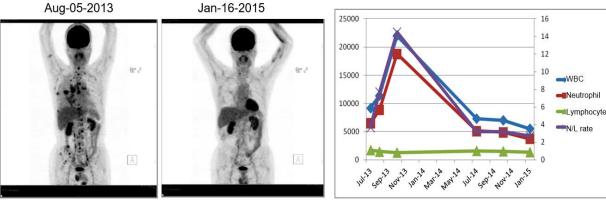
In the clinical phase I/II tests carried out in the U.S., the drug was effective for 48% (14/29) of patients in the phase II, indicating high effectiveness. Seeing this result, the company had a meeting with the U.S. Food and Drug Administration (FDA) after the clinical phase II test, and submitted a plan for the clinical phase III test, and then obtained a consent. Then, the company is selecting facilities for clinical tests. 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. Inside Japan, Nippon Shinyaku Co., Ltd., which is the licensee of the drug, is preparing for the clinical phase I test.



2) 「DFP-14323」

Item	Outline		
Target disease	Lung cancer, etc.		
Characteristics of existing	The existing medicine "bestatin (Ubenimex)" is targeted at blood cancer. The dosage is high,		
medicines, etc.	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	For the purpose of enhancing the antitumor effect, the dosage was reduced, and the drug was		
of modules	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.		

[Clinical Results: DFP-14323+EGFR-TKI with lung cancer < PET scan and blood immunomaker change >]



Patent No. PCT/JP2015/083119

(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 in January 2018 in Japan for additional indication, and is proceeding with the registration of cases.

The company aims to obtain approval for the addition of supplemental indication and sell it in Japan by fiscal 2021.

The company has concluded a contract for an exclusive license in Japan with Kyowa Chemical Industry Co., Ltd. (unlisted).

3) 「DFP-11207」

3) 'DFT-11207]	
Item	Outline
Target disease	Solid tumors (such as pancreatic cancer)
Characteristics of	The existing medicine TS-1 has hematotoxicity, including the reduction of blood platelets, and it
existing medicines, etc.	is difficult to continue treatment sufficiently.
Improved points and	DFP-11207 is a compound developed by combining three modularized active substances (modules
effects of 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.



(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.

The test for studying the effects of meals has been finished, and the company is summarizing the results and preparing for the clinical phase II test.

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

4) 「DFP-14927」

Item	Outline
Target disease	Solid tumors and blood cancer
Characteristics of	The existing medicine DFP-10917 needs to be administered for 14 days in a row, by using a
existing medicines,	pouch for continuous intravenous injection, and it was necessary to improve its convenience.
etc.	The target disease has been only blood cancer.
Improved points	DFP-14927, a polyethylene glycol-conjugated candidate anticancer substance, is a polymeric
and effects of	delivery of DFP-10917. It selectively clusters around cancer tissue, and discharges DFP-10917
modules	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.

(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.

Seeing this result, the company plans to start the clinical phase I test targeted at patients of digestive system cancer, including pancreatic and stomach cancers. In addition to the clinical test, the company plans to discuss the possibility of administration to patients of blood cancer, including myelodysplastic syndrome.

5) 「DFP-10825」

Item	Outline
Target disease	Peritoneal dissemination metastatic cancer (stomach cancer, ovarian cancer)
Characteristics of	Although the basic drug siRNA has a definite inhibitory effect as its basic effect, its clinical
existing	effect in systemic administration has been poor.
medicines, etc.	
Improved points	Nucleic acid drugs using RNA interference are expected to be the next cancer treatment drugs
and effects of	next to molecular-targeted cancer drugs and cancer immunotherapeutic drugs. The nucleic acid
modules	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.

(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.

6) 「DFP-17729」

Item	Outline	
Target disease	Solid cancer, etc.	
Characteristics of	Urinary alkalinizing agents, which are existing drugs, are targeted for hyperuricemia and others,	
existing	but it has been confirmed that they provide a life-prolonging effect in pancreatic cancer and have	
medicines, etc.	an antitumor effect on each cancer tumor.	
Improved points	Normal cells are more alkaline outside the cells than inside the cells, but cancer cells are more	
and effects of	acidic outside the cells. This is because the growth of cancer cells promotes glycolysis,	
modules	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.	

(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 combined use of anti-cancer agents and immune checkpoint inhibitors and provide new cancer treatments.

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 March 2019 Earnings Forecast

	FY 3/18	FY 3/19	Year on year
		(Estimate)	
Operating Revenue	150	200	+33.3%
Operating Income	-243	-682	-
Ordinary Income	-244	-739	-
Net Income	-246	-741	-

Unit: Million yen

(Operating Revenue)

As the clinical phase III test for DFP-10917 will begin in the U.S., the company will start the clinical phase I test in Japan. Accordingly, it is estimated to receive an operating revenue of 200 million yen as a milestone from Nippon Shinyaku Co., Ltd.

(Operating income)

The R&D expense for the clinical phase III test for DFP-10917 in the U.S. and the clinical phase II test for DFP-14323 in Japan, and for preparing for the clinical phase II test for DFP-11207 in the U.S. and the clinical phase I test for DFP-14927 in the U.S., is estimated to be 692 million yen, up 247.2% year on year, and the remuneration paid to lead managing underwriters, audit corporations, etc. is projected to be 45 million yen, up 16.2% year on year (116.2% compared with the previous term).

The SGA, including the R&D expense, is forecasted to increase 124.1% year on year to 882 million yen, due to further expansion of the business operation for drug pipelines, and operating loss is estimated to be 682 million yen, up 439 million yen year on year.

2-2 Financial Conditions

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	End of Mar.	End of Dec.		End of Mar.	End of Dec.
	2018	2018		2018	2018
Current Assets	831	3,686	Total Liabilities	41	46
Cash	781	3,655	Total Net Assets	822	3,674
Noncurrent Assets	32	34	Retained Earnings	-1,392	-1,896
Property, Plant and	30	31	Total Liabilities, Net	864	3,721
Equipment	30		Assets		
Total Assets	864	3,721	Balance of Short and	19	14
			Long-Term Debts	19	14

Unit: Million yen

Cash and net assets increased from the end of the previous term due to a public stock offering. Total assets grew 2,857 million yen from the end of the previous term to 3,721 million yen. Capital-to-asset ratio was 98.7%, up 3.5 points from the end of the previous term.

3. Interview with President Eshima

We interviewed President Eshima about the company's strengths and characteristics, his thoughts on module drug development, and messages to shareholders and investors.



Q: "Please tell us about the strengths and characteristics of your company as a bio-venture, and its competitive advantage."

A: "We are a very small company but have a management team of experienced members who have been involved with research and development and clinical practice. Our major strength is that we can embody the ideas of module drug development by utilizing the experiences of our members to achieve our mission of 'To provide treatment methods recommendable to cancer patients among relatives with peace of mind."

We have just over 10 employees and are small compared to the other listed bio-venture companies, but our management team is made up of experienced members who have been engaged in research and development at pharmaceutical companies and involved with clinical practice at famous universities and research institutes in Japan and overseas. We truly understand the role of pharmaceutical companies for patients and their families, and do not just develop drugs to shrink "cancer." Our major strength is that we can embody the ideas of module drug development and commercialize them by utilizing the experiences of our members to achieve our mission of "To provide treatment methods recommendable to cancer patients among relatives with peace of mind."

Q: "What are the benefits of module drug development to patients and the importance for your company?" A: "In addition to reducing side effects, we believe that module drug development will enable us to provide more overall benefits to the patients through reduction in drug prices. Meanwhile, module drug development is an important development concept for us as it will lead to the realization of sustainable growth."

I encountered many cancer patients in my many years of experience and observed many side effects.

Although side effects are common to anti-cancer drugs, some cases have problems with administration methods. Looking at patients and their families, I realized that there were actually not so many cases where treatments were truly intended to benefit the patients. The room for improvement will be extremely large.

Major pharmaceutical companies rarely review the drugs that are already in the market. This means that there are many opportunities for commercialization through module drug development for our company, which places the first priority on the benefits for patients. In addition to reducing side effects, we believe that we can provide overall patient benefits through reduction of drug prices.

At the same time, we consider module drug development as an important development concept that will lead us to the realization of sustainable growth.

The most important factor for a bio-venture to last as a company is to drive science and development in a balanced manner. However, it seems that some bio-ventures have been unable to survive as a result of overemphasizing science. Regarding this issue, module drug development permits us to achieve a good balance between science and development as well as efficient and speedy product development of effective drugs, even though the scale of the company is small. Therefore, we believe that it will bring great benefits both to the patients and us.

Q: "Please share your message to shareholders and investors."

A: "All of us will join hands to support those who are suffering from cancer. We would appreciate your support from the mid/long-term viewpoint."

I observed some unhappy cases in "cancer treatment," where the patients were hit by the treatment and unfortunate results occurred, because the treatment was too focusing on hitting "cancer." We want as many patients and families as possible to become happy by providing treatment methods that are safer, can achieve longer life, and are economically acceptable, instead of focusing on just hitting cancer.

As our company has just been listed, it is necessary to take a little more time to obtain approval and sell our products, but all of us will join hands to support those who are suffering from cancer. We would appreciate your support from the mid/long-term viewpoint.



4. Conclusions

Module drug development could be imitated by other companies, but Delta-Fly Pharma has been solely producing some results, by launching 6 pipelines, out of which 3 drugs are undergoing clinical tests and one of them are going to undergo a final clinical test. This has been realized by their development capability based on the unique ideas and ingenuity of an experienced development team led

by the President Eshima. This differentiates the company sharply, giving unwavering competitive advantage.

In order to achieve sustainable growth, it is indispensable to further enhance the capability of development. Accordingly, we would like to pay attention to their efforts to strengthen their business base, including the development of organizations, and their progress.

On the other hand, they aim to obtain approval for DFP-10917, which has made the most development progress, and release it in the U.S. by fiscal 2022, so it takes some time to commercialize it and earn profits, but we hope that they will proceed swiftly with the development of products, which are socially meaningful as they will improve the quality of life for patients and their family members and reduce social loss.

< 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 3 outside ones	

©Corporate Governance Report

The latest update: October 12, 2018.

<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 (Excerpts)>
It is written that "We follow all of the basic principles."

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