BRIDGE REPORT Bridge Salon

President & CEO, Yoshihiro Arai

Solasia Pharma K.K. (4597)

Solasia

Company Information

Market	TSE Mothers
Industry	Pharmaceutical products (manufacturing)
President	Yoshihiro Arai
HQ Address	4F SUMITOMO FUDOSAN SHIBA-KOEN TOWER, 2-11-1, Shiba-koen, Minato-ku, Tokyo
Year-end	December
Homepage	https://solasia.co.jp/en/

Stock Information

Share Price	Shares Outstanding (End of term)		Total market cap	ROE Act.	Trading Unit
¥166	123,081,210 shares		¥20,431 million	-78.1%	100 shares
DPS Est.	Dividend yield Est.	EPS Est.	PER Est.	BPS Act.	PBR
¥0.00	-	¥ -22.83	-	¥29.78	5.6x

*The share price is the closing price on March 22. The numbers were the value from the financial results of FY 12/20. EPS represents the lower limit of the forecasted range.

Earnings Trends

Fiscal Year	Sales	Operating Profit	Ordinary Profit	Net Profit	EPS	DPS
December 2017 Act.	410	-1,009	-1,016	-1,007	-12.24	0.00
December 2018 Act.	318	-2,420	-2,445	-2,422	-25.98	0.00
December 2019 Act.	1,310	-1,762	-1,797	-1,867	-17.75	0.00
December 2020 Act.	454	-4,116	-4,159	-4,127	-35.16	0.00
December 2021 Est.	1,600 ~ 2,600	-2,800 ~ -1,800	-2,800 ~ -1,800	-2,800 ~ -1,800	-22.83 ~ -14.68	0.00

* The forecast is from the company. IFRS application. Net income is profit attributable to owners of the parent. Hereinafter the same shall apply.

This report outlines Solasia Pharma's Fiscal Year December 2020 earnings results and forecasts for the fiscal year December 2021 etc.

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Key Points

- **The sales revenue for FY December 2020 was 454 million yen, down 856 million yen year on year. It is composed of mainly the product sales of Sancuso® (SP-01) and episil® (SP-03). The sales of the two products were affected by the decrease of visits of medical representatives (MRs) to hospitals and the restrictions on marketing activities and surveys after the release of products due to the novel coronavirus. The lump-sum revenue from the contract for licensing out SP-04 was posted in the previous term, but in FY December 2020, the negotiation for licensing did not progress due to the restriction on overseas travel. R&D expenses was 1,928 million yen, up 789 million yen year on year. Seeing the results of the phase III clinical trial of PledOx® (SP-04), the allowance for development costs was posted, and the R&D expenses exceeded the initial estimate. SG&A expenses was 2,432 million yen, up 564 million yen year on year. It was below the initial estimate, excluding the impairment loss for SP-04 amounting to 800 million yen. As a result, operating loss augmented 2,353 million yen year on year to 4,116 million yen.**

- **The sales revenue for FY December 2021 is estimated to be "1.6 billion yen to 2.6 billion yen", significantly increasing from 450 million yen in the previous term, and operating loss is projected to decrease, too. Sales revenue will be composed of the product sales of Sancuso® (SP-01) and episil® (SP-03) as well as part of the revenues from the licensing for darinaparsin (SP-02) and/or arfolitixorin (SP-05). The operating profit, excluding the R&D expenses and depreciation on which the company puts emphasis, is estimated to be ranging from "negative 350 million yen to positive 650 million yen", the upper estimate hitting a record high. We are willing to see whether the company will be able to license out darinaparsin (SP-02) and/or arfolitixorin (SP-05).**

- **The company announced the interim analysis results for the phase III clinical trial of arfolitixorin (SP-05). No problems were reported regarding safety or efficacy, and the continuation of the trial with the minimum target number of 440 cases was recommended. Upon receiving this recommendation, the company may be able to proceed with development in the shortest period by continuing the trial with the minimum number of cases. The company plans to obtain topline results in the first half of 2022, and apply for New Drug Approval to the authorities in the second half of 2022.**

- **In FY December 2020, their business progressed significantly as the company announced positive results of the final clinical trial of darinaparsin (SP-02), introduced the rights for SP-05 and conducted fund procurement for it, and launched episil® (SP-03) in South Korea, but the results of the global phase III clinical trial of PledOx® (SP-04) were not positive unfortunately, as they were not able to satisfy major evaluation items for efficacy and impairment loss was posted.**

- **The outlook for PledOx® (SP-04) is still unclear, but impairment loss has been already posted, and it seems that the stock market is reacting to the following developments. According to the company, famous institutional investors inside and outside Japan, which did not consider the company as an investment target, are increasing their interests in the company.**

- **The operating profit, excluding the R&D expenses and depreciation, for this term is estimated to be at the most, up to 650 million yen, hitting a record high. We are willing to see whether the company will be able to license out darinaparsin (SP-02) and/or arfolitixorin (SP-05).**

1. Company Overview

As a specialty pharma* specializing in oncology, Solasia Pharma develops and sells medicines for cancer treatment and supportive care, etc. in Asia, mainly Japan and China, each of which has a promising market.
Its significant strengths and features are the development staff with abundant practical experience led by CEO Arai, high rate of successful development, the stable business foundation, feasibility of business model, and so on.
*Specialty Pharma: A new drug developing enterprise possessing research and development capabilities which has a certain standard in its field of expertise, both domestically and internationally.

1-1 Corporate History

Its predecessor is JapanBridge Inc., which was established as a foothold for preparing for the business of developing pharmaceutical products in the U.S. in December 2006 jointly by ITOCHU Corporation and MPM Capital, a U.S. venture capital specializing in bio business.

In May 2008, the company introduced the exclusive right to develop and sell the first product "Sancuso® (SP-01)" in Japan, Taiwan, Singapore, Malaysia, and China, including Hong Kong and Macau.
In September 2008, the company was renamed Solasia Pharma K.K.
Then, the company introduced the exclusive right to develop and sell "darinaparsin (SP-02)" in the Asia-Pacific region (March 2011), introduced the exclusive right to develop and sell it around the world, including the U.S. and Europe (July 2014), and introduced the exclusive right to develop and sell "episil® (SP-03)" in Japan and China (March 2015), to enrich pipelines. The company also provided Kyowa Kirin Co., Ltd. with the exclusive license to develop and sell "Sancuso® (SP-01)" in Taiwan, Hong Kong, and so on. (February 2010), provided Meiji Seika Pharma Co., Ltd. with the exclusive license to develop and sell "darinaparsin (SP-02)" in Japan (January 2015), and provided Lee's Pharmaceutical (HK) Limited with the exclusive license to sell "Sancuso® (SP-01)" in China (excluding Beijing, Shanghai, Guangzhou, Hong Kong, and Macau). All these paved the way for monetization.

In 2016, the company applied for the approval for manufacturing and sales of medical apparatus for "episil® (SP-03)" in China and Japan, and provided Meiji Seika Pharma Co., Ltd. with the exclusive distributorship in Japan and provided Lee's Pharmaceutical (HK) Limited with the exclusive distributorship in China (excluding Beijing, Shanghai, and Guangzhou).

As the company was expected to grow as a pharmaceutical company specializing in cancer, it was listed in Mothers of Tokyo Stock Exchange in March 2017.

In November 2017, the company acquired the exclusive right to develop and sell for "PledOx® (SP-04)" in Japan, China, South Korea, Taiwan, Hong Kong, and Macau. In August 2020, it also introduced exclusive right to develop and sell for "arfolitixorin (SP-05)" in Japan, and currently has five pipeline products.

In May 2018, "episil® (SP-03)" was released in Japan, as the first product released by the company. In 2019, the company released "Sancuso® (SP-01)" and "episil® (SP-03)" in China, and "episil® (SP-03)" in 2020 in South Korea. Namely, the company is making a transition from the "development" stage to the "sales and commercialization" stage.

1-2 Corporate Philosophy・Management Philosophy

The company's name, SOLASIA, is a coined word combining Sol (the Sun in Latin) and Asia (Asian counties). It represents the company's mission which is to be the Sun brightening the future of various people facing many challenges of cancer in Japan and other Asian countries.
The management philosophy adopts the following mission, vision, and values.

Role to Fulfill (Mission)	* Better medicine for a brighter tomorrow
Ideal Situation (Vision)	* To be recognized domestically and overseas and gain a high level of trust from all stakeholders. * To be recognized as a specialty pharma developing innovative medicine, where each employee possesses passion, ambition, and a sense of morality, strives to better themselves, maintains a high level of expertise, and continuously endeavors for new value and creation for the future.

	* To meet the needs of people (medical practitioners and patients) who need our products and contribute to them.
Shared Values (Value)	* Create value for patients. * Have high ethical standards. * Trust and respect each other. * Work as a team.

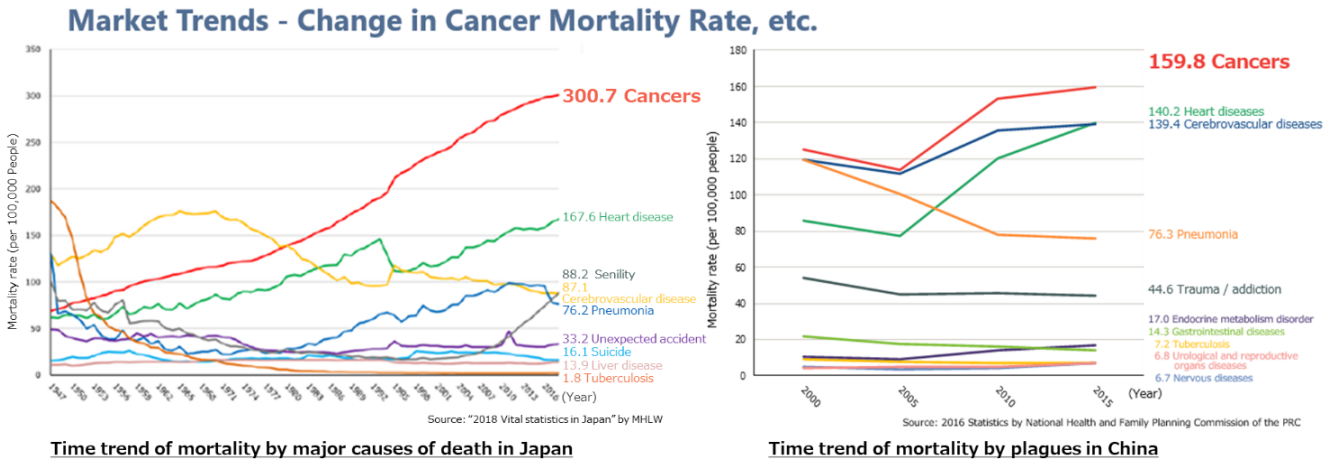
In addition, the following two points are listed as management policy.

①	For the time being, we will continue the in-licensing of new products in cancer and rare disease field where major pharmaceutical companies do not emphasize from a performance-based approach and contribute to patients without adequate medication.
②	Through the commercialization of products, we will promptly establish the financial stability needed to realize our management philosophy, and secure independence.

The company will focus on developing new drugs to solve unmet medical needs (medical needs for diseases for which no treatment has been developed), which is a niche market but has many troubled patients.
As research and development is proceeding, they will have to rely on financing CF now, but they plan to make operating CF positive soon and build a strong basis to achieve continuous growth.

1-3 Environment Surrounding Solasia Pharma

According to "Vital Statistics, 2018" published by the Ministry of Health, Labour and Welfare, in 2016, the leading cause of death was malignant neoplasm (cancer), 300.7 per 100,000 people.
In 1981, cancer overtook cerebrovascular diseases, the former number one cause of death, with the mortality rates from cancer being 142.0 and that from cerebrovascular diseases being 134.3. Since then, cancer has been the leading cause of death for the 30 consecutive years and keeps going up every year.
As it is said that the incidence rate of cancer is rising due to aging and changes in lifestyles including diet, the number of patients and deaths regarding cancer is rising in China as well.



(Source: Solasia Pharma)

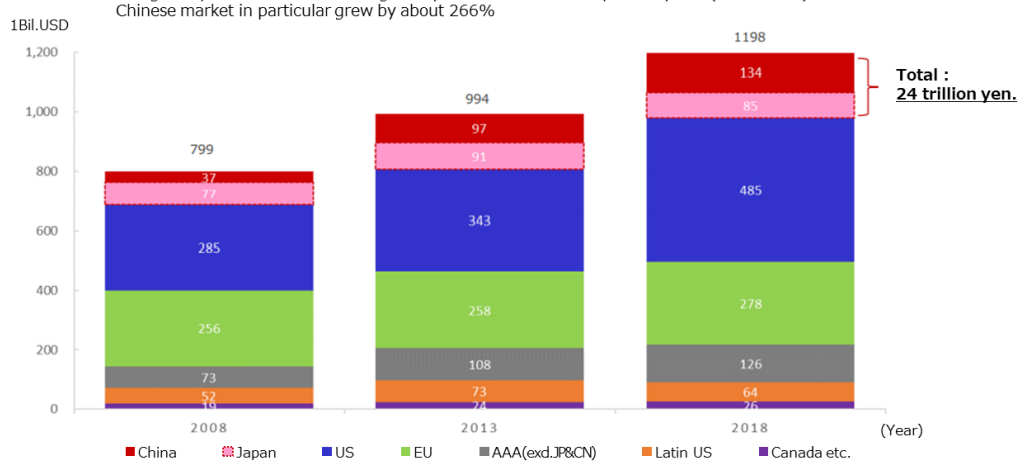
Currently, the U.S. has the biggest pharmaceutical market, followed by China after it overtook Japan. The global pharmaceutical market grew by about 50% over the past 10 years (2008-2018), but the Chinese market grew by about 266%, well above the overall market.
In the future, it is said that the market in China will expand to the point where it will share the top position with the U.S.
The total market size of China, the second biggest country, and Japan, the third biggest country, is 24 trillion yen. For the time being, this huge market will be the company's main target.

World's pharmaceutical market ranking

No.1-US,No.2-China,No.3-Japan

Change in pharmaceutical sales market

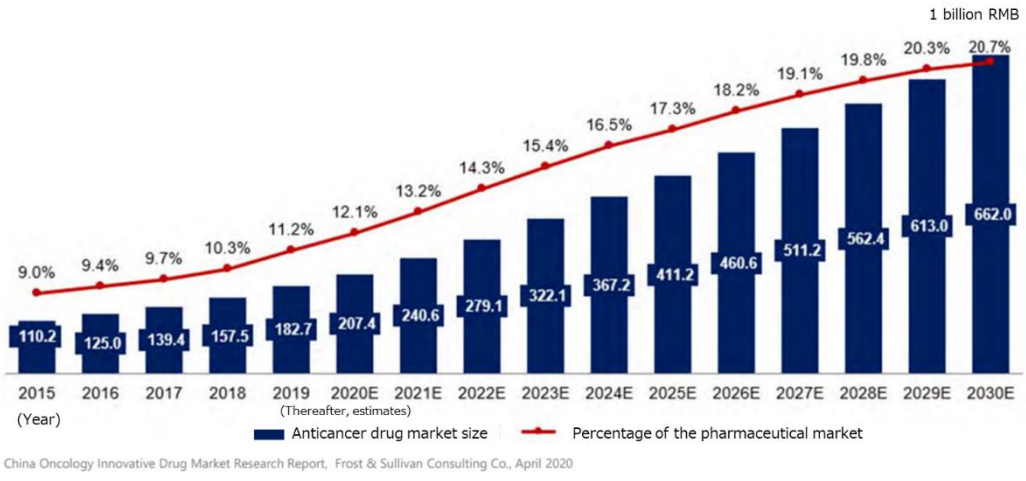
The global pharmaceutical market grew by about 50% over the past 10 years (2008-2018)
Chinese market in particular grew by about 266%



(Source: Solasia Pharma)

The anticancer drug market in China is over 3 trillion yen, accounting for more than 10% of the total pharmaceutical market, and it has grown at a CAGR of approximately 14% over the past five years.

Current Status and Future Trends of Anticancer Drug Market in China



Source： China Oncology Innovative Drug Market Research Report, Frost & Sullivan Consulting Co., April 2020

- ✓ China's anticancer drug market is expected to grow to 3.3 trillion yen* by 2020 and 10.6 trillion yen* by2030
- ✓ China's anticancer drug market is growing at about 14% annually (past 5 years)
- ✓ The share of China's anticancer drug market in the total Chinese pharmaceutical market is also on the rise.

*Converted at 1 Chinese yuan (RMB) = 16 yen.

(Source: Solasia Pharma)

As the mortality rates from cancer increases as shown above, expectations for "new anticancer drug" and "cancer supportive care" are growing all over the world.

(New anti-cancer drug)

In cancer treatment provided using anticancer drug, it is said that a majority of hospitals use the polytherapy which uses multiple anticancer more than the monotherapy which uses a single anticancer drug.

In addition, although it depends on cancer types, there is significant risk of relapses. Besides, in case of intractable cancers, it is difficult to cure such cancers only with a single treatment method, which means that a single medicine is not always an absolute cure, and therefore, other therapeutic medications will hardly be direct "competing products."
Molecular targeted drugs and immunotherapy have also attracted attention in recent years, however chemotherapeutic agents still hold an important position for treatment of many cancer types. Standard therapy involves a regimen containing a cytotoxic anticancer drug, for which a high medical demand is expected in the future as well.

(Cancer supportive care)
Anticancer drugs are potent medicine that attacks cancer cells, and side effects are inevitable.
If the side effects on patients cannot be controlled, anticancer therapy through drug administration must be stopped, which has a risk of resulting in cancer progression.
As a result, expectations for drugs and medical devices which control such side effects are increasing in order to avoid treatment discontinuation and complete cancer treatment.
In addition, while therapeutic drugs for cancer must be approved for each cancer type, supportive care can be provided to a wide range of patients regardless of cancer types, which means that there will be strong needs and markets.

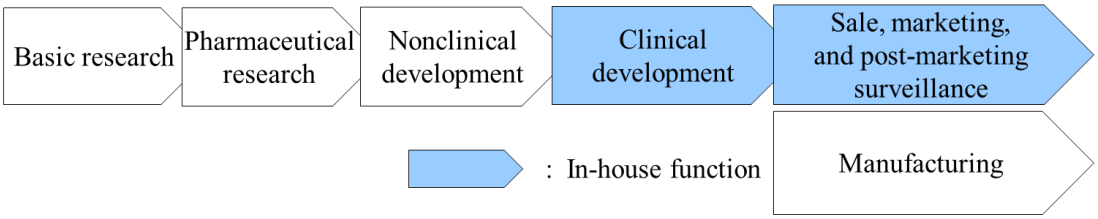
In summary, needs for cancer treatment in Japan and China are growing and there are great expectations for new anticancer drugs and cancer supportive care. Solasia Pharma is establishing business model and business strategy to incorporate such needs and boost earnings.

1-4 Business Description

(1) Business Model

Before the launch of new medicines, it is usual to go through the processes spanning from "basic research" to "pharmaceutical research," "nonclinical development (tests conducted using animals to examine medicinal and pharmacological action, in-vivo pharmacokinetic properties, adverse effects, etc.)," and "clinical development (scientific tests carried out to examine the effects of pharmaceuticals and treatment techniques on human beings), obtain approval from the authorities, and then conduct "manufacture" and "sales, marketing, and post-marketing surveillance."
Although major pharmaceutical companies are propelling outsourcing to CROs at the stage of clinical development to make considerable amounts of research and development costs variable, they basically perform all of the above-mentioned processes internally.
Such a system has supported high profitability of pharmaceutical companies. The life science field, however, is currently advancing and becoming complicated and diverse at a rapid rate, and there is an increasing possibility that each company's unique drug discovery technology quickly becomes obsolete.
In addition, there are a myriad of cases where practical application of new drugs is given up before clinical development, regardless of costs and time spent from the stage of basic research, and therefore new drug is not established in the end. In other words, pharmaceutical development is facing high risks at all times.

Accordingly, Solasia Pharma does not conduct the processes from basic research to nonclinical development on its own which has high failure rate. By in-licensing promising pharmaceuticals that are still under development from outside companies, it embarks on development starting from clinical development. It utilizes its strength and reduces risk by focusing management resources on the business activities subsequent to the development stage.
At the moment, it plans not to do manufacturing due to the large cost burden.



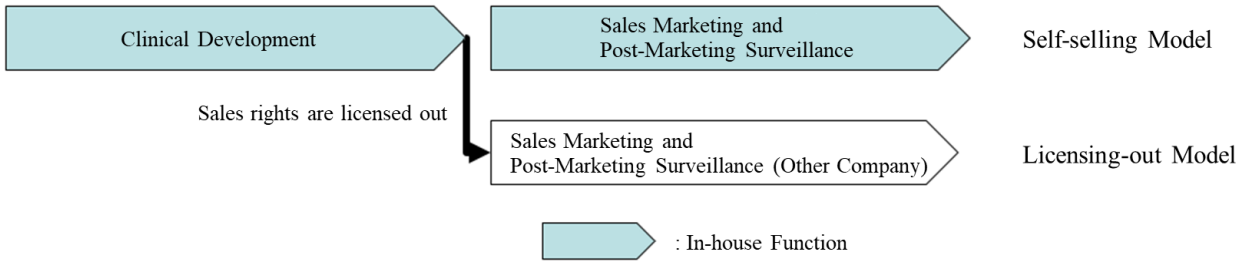
(Source: Solasia Pharma)

Regarding the sales and marketing structure, the company has set up a system that takes into account the balance between high profitability and risk control.
In general, pharmaceutical companies hold gross profit margins to high standards, which is considered to be attained by their in-house manufacture and sales activities.

	Sales Revenue	Gross Profit	Gross Profit Margin
Astellas Pharma	1,300,843	1,024,104	78.7%
Daiichi Sankyo	981,793	638,586	65.0%

*Unit: million yen. The values are the results from FY March 2020.

On the other hand, coverage of sales territories (e.g., to cover all over Japan) is required for pharmaceuticals, and therefore, a rise in fixed costs is inevitable for establishing a company's own sales network.
Accordingly, Solasia Pharma uses both "self-selling model" and "licensing-out model" (sales rights are granted to other companies for pharmaceuticals that have completed clinical development).



(Source: Solasia Pharma)

(Self-selling model)
The current major licensing-out partners are the following three companies.

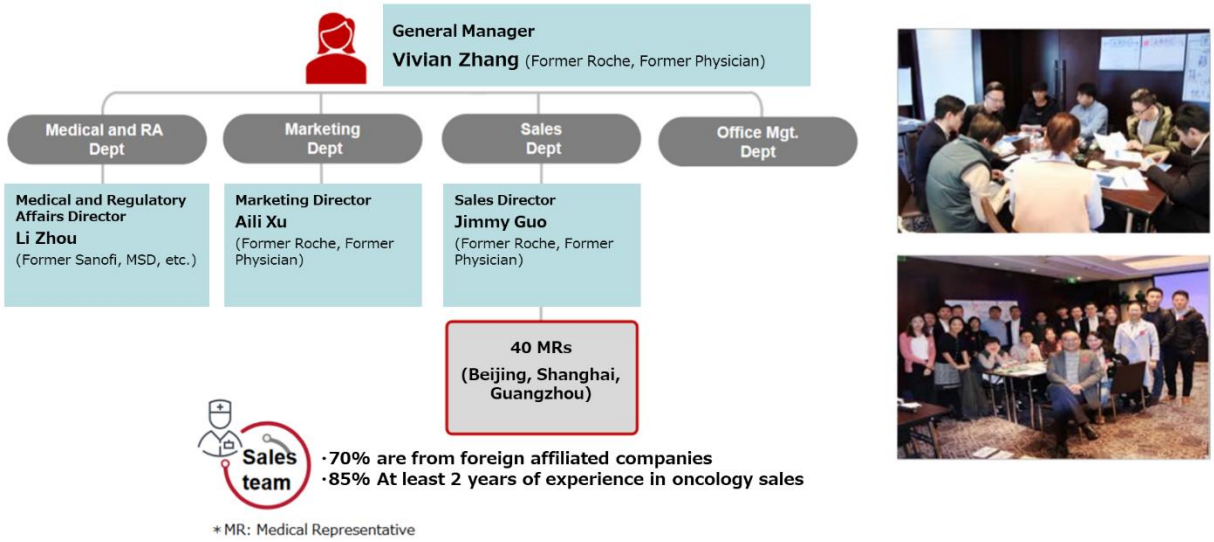
Meiji Seika Pharma Co., Ltd.	* A pharmaceutical company of the Meiji Group. It is a specialty pharma in the fields of cancer, infections, and the central nervous system and has yielded sales results of multifarious products in the cancer field. * Japanese partner with the rights of "darinaparsin (SP-02)" * Japanese partner with the rights of "episil® (SP-03)"
Lee's Pharmaceutical (HK) Limited	* A Chinese pharmaceutical company listed on the Hong Kong market. It sells multiple pharmaceutical products in fields including the cancer field across China through about 30 bases. * Chinese partner with the rights of "Sancuso® (SP-01)" (excluding Beijing, Shanghai, and Guangzhou) * Chinese partner with the rights of "episil® (SP-03)" (excluding Beijing, Shanghai, and Guangzhou)
Maruho Co., Ltd.	* A pharmaceutical company that was founded in 1915 and engages in the research, development, production, and sale of pharmaceutical products, etc. It is especially excellent in the dermatological field. * Partner for the Japanese right of "PledOx® (SP-04)"

Solasia Pharma plans to create licensing-out partnerships with a focus on mid-sized pharmaceutical companies which it can fall in line easily and forge win-win relationships.

(2) Marketing structure in China
The company, which is aiming to develop a huge Chinese pharmaceutical market, will build a self-selling structure and carry out the self-selling business model with an aim of maximizing product sales profit and managing fixed costs in three major cities in China, "Beijing, Shanghai, and Guangzhou."
Self-selling activities in China are handled by Solasia Medical Information Consulting (Shanghai) Co. Ltd., which is a wholly owned subsidiary of Solasia Pharma.

Although the total population of the 3 cities accounts for only about 5% of the entire population of China, a number of large hospitals with advanced medicine which uses anticancer drugs are located in the above 3 cities, making them huge markets which account for 30% of the Chinese anticancer drug market.
Furthermore, whether new pharmaceuticals are used and popularized depends highly on judgment and decision made by influential doctors, and thus, it is extremely important to make sales activities targeting large hospitals where such influential doctors work.
In addition, such self-selling activities will be done not in a large scale throughout China but in a small scale in each of the 3 cities, which makes it possible to cover with a relatively small number of staff.

Point 1: Experienced management team
The marketing and sales departments of the company's wholly owned subsidiary Solasia Medical Information Consulting (Shanghai) Co. Ltd., which was established in 2014 and engages in company's own marketing in China, are led by the following 4 people in charge.



(Source: Solasia Pharma)

Position	Name	Background
General Manager	Vivian Zhang	Former Roche, Director of Oncology Business Unit, etc., Physician (former Shanghai Ninth People's Hospital)
Marketing Director	Aili Xu	Former Roche, BMS, Sanofi, etc. Physician (former Shanghai First People Hospital, Emergency department)
Sales Director	Jimmy Guo	Former Roche, BI, etc. Physician (former Suzhou City Hospital, Cardiac Surgeon)
Medical and Regulatory Affairs Director	Li Zhou	Former Sanofi, MSD

Dr. Vivian Zhang, the president of the subsidiary, worked at a university hospital for 4 years as a clinician, and then worked at a pharmaceutical company for 26 years, gaining a wealth of experience mainly in the oncology field. Above all, at Roche, a global pharmaceutical company, she achieved excellent sales results with well-known, powerful anticancer drugs that are leaving their names on the history of anticancer drugs such as Herceptin (antineoplastic drug), Tarceva (antineoplastic drug), and Avastin (antineoplastic drug) as well as antiemetics Kytril (granisetron hydrochloride) that prevents side effects in anticancer drug treatment. She was in charge of the anticancer drug business.
Dr. Aili Xu, Dr. Jimmy Guo, and Mr. Li Zhou are also from Mega Pharma and have extensive experience.

Under these experts, a total of approximately 40 MRs are employed in Shanghai, Beijing, and Guangzhou. 70% of them are from major foreign-affiliated pharmaceutical companies and have an average of more than two years of sales experience in the cancer field.
The company operates a strong marketing and sales force under an experienced management team.

Point 2: Highly regarded by Chinese medical community

The judgement and decision of influential physicians greatly affect the outcome of the use and distribution of new medicines, and China is no exception.

Under these circumstances, "Sancuso® (SP-01)" is already recommended as one of the standard treatments for nausea and vomiting in the Chinese version of the NCCN guidelines for cancer treatment, which is referenced in the clinical sites.

In addition, at Chinese Society of Clinical Oncology (CSCO), prominent clinicians who are leading the field of cancer treatment in China highly valued "Sancuso® (SP-01)" for its feature of easily suppressing nausea and vomiting in the entire chemotherapy process. In response to this, "Sancuso® (SP-01)" is listed as a standard antiemetic treatment option for cancer treatment in the first guideline for proper use of antiemetics issued by CSCO.

The company is receiving such a high rating because of the superior efficacy of "Sancuso® (SP-01)". But it is obvious that the strong relationship with the Chinese clinical network that the management team had been building since their times with Roche is also playing a key role, and it is a major advantage of the company that other bio-ventures do not have.

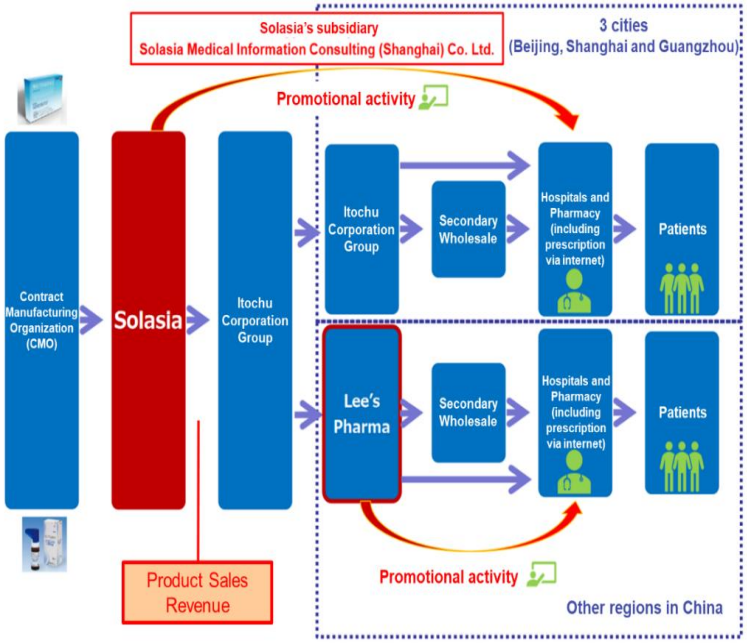
Point 3: Current status and the future of marketing activities

The company has completed establishing the self-selling system for "Sancuso® (SP-01)" and "episil® (SP-03)" by placing bases in 3 cities and employing a total of 40 MRs.

In these cities, the company covers over 70 large hospitals where influential physicians work and promote sales expansion by diffusing information.

First, it is necessary to open an account in each hospital or hospital pharmacy, and general pharmacy. So far, accounts have been opened in about half of these targets. Both products have not yet been covered by NRDL (China's National Reimbursement Drug List), so the rise in sales amount is still slow, but the company is expecting to accelerate the speed as more accounts are opened in the future.

"Sancuso® (SP-01)" and "episil® (SP-03)" in other Chinese regions will be sold by Lee's Pharma, the sales contract partner.

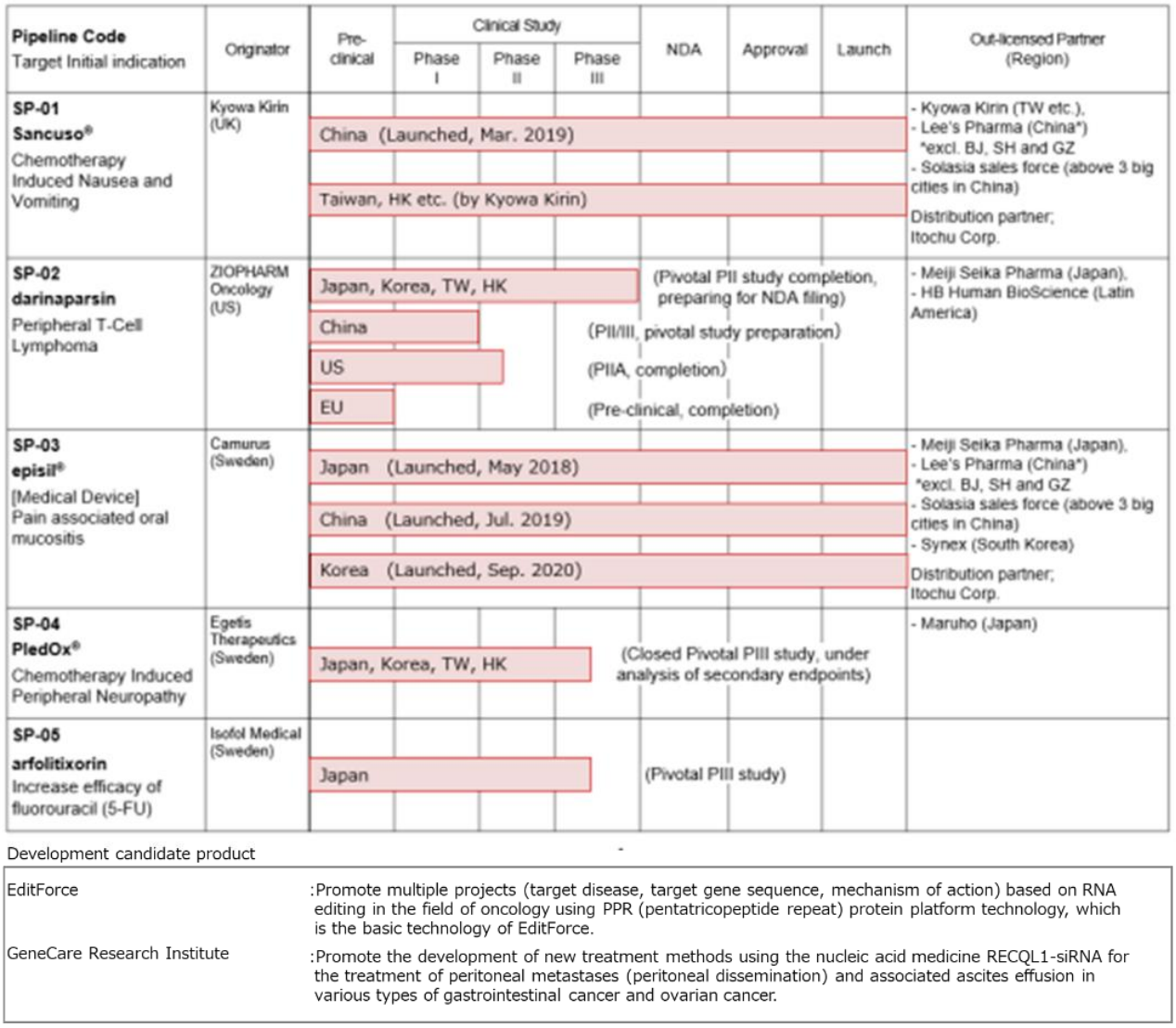


(Source: Solasia Pharma)

(3) Products/Development Pipeline

Solasia Pharma currently owns the following 5 products/development pipelines in accordance with the above-mentioned management policy.

History of development pipeline and operationalization, current situation and future projection are as follows. (As of February 10, 2021)
In addition to SP-05 introduced in 2020, the company is striving to enrich pipelines. The target area is basically the cancer-related one, but the company will enhance the research function by the collaborative research with the alliance partners: EditForce and GeneCare Research Institute, in addition to the introduction from the outside, and aim to expand the target area.



Development candidate product

EditForce	:Promote multiple projects (target disease, target gene sequence, mechanism of action) based on RNA editing in the field of oncology using PPR (pentatricopeptide repeat) protein platform technology, which is the basic technology of EditForce.
GeneCare Research Institute	:Promote the development of new treatment methods using the nucleic acid medicine RECQL1-siRNA for the treatment of peritoneal metastases (peritoneal dissemination) and associated ascites effusion in various types of gastrointestinal cancer and ovarian cancer.

(Source: Solasia Pharma)

1) "SP-01: Transdermal Delivery System Sancuso®" (Sales name in China: 善可舒®)

Item	Overview
Efficacy/effect	Chemotherapy Induced Nausea and Vomiting (CINV)
Characteristics/Strength compared with competitive drugs	* The world's only transdermal patch type 5-HT3 receptor antagonist * The effect per administration (patch) lasts for 5 days, which covers the administration period of the general chemotherapy regimen (provided for 1 - 5 days). It can also be used for outpatients. * In June 2019 (3 months after its launch), it was listed as a standard antiemetic treatment option for cancer treatment in the first guideline for proper use of antiemetics issued by CSCO.

（※）CSCO(Chinese Society of Clinical Oncology) : The most prominent and largest academic conference related to cancer in China

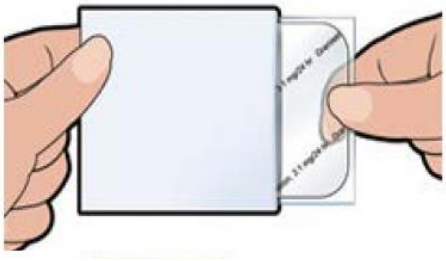
◎Overview of indications

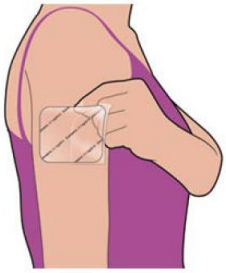
Nausea and vomiting are widely known as typical side effects caused by anticancer drug.

Administration of anticancer drug damage cells called Chromaffin cells in the small intestine.
The damaged Chromaffin cells produce serotonin, a neurotransmitter, which is taken in by the 5-HT3 receptors in the peripheral vagus nerve. This stimulus is transmitted through the peripheral vagus nerve to the medulla oblongata via the chemoreceptor trigger zone (CTZ) in the area postrema of the fourth ventricle of the brain, stimulating the vomiting center which gives living organisms commands to develop nausea and vomiting, and then symptoms of nausea and vomiting appear.
It is necessary to disrupt the stimuli generated by serotonin to the 5-HT3 receptors in order to control nausea and vomiting. There are a variety of "5-HT3 receptor antagonists" which are drugs used for the above purpose, and one of the representative agent is Granisetron.

◎Overview of "Sancuso® (SP-01)"

"Sancuso® (SP-01)" is a transdermal 5-HT3 receptor antagonist containing Granisetron and is the world's only patch-type antagonist.





*Chinese package of Sancuso®
(Source: Solasia Pharma)

Anticancer drugs are administered over 5 days in most cases, but injections and oral antiemetic agents are effective only for about 1 to 2 days and must be injected multiple times within the anticancer drug administration period. On the other hand, "Sancuso® (SP-01)" maintains the concentration level of Granisetron in blood on a stable basis for 5 days. Therefore, once a patch of "Sancuso® (SP-01)" is attached, there is no need to add antiemetics, which enables cancer treatment not through hospitalization but through outpatient care and contributes significantly to the improvement of patients' quality of life.

Another advantage is that transdermal type drugs can be administered even to patients who are facing difficulty in taking oral medicines due to various symptoms including nausea, vomiting, and stomatitis. Earning reputation for the above-mentioned advantages, "Sancuso® (SP-01)" is recommended for prescription in the American NCCN clinical practice guidelines and the Chinese clinical practice guidelines.

◎Current situation of development and commercialization

Currently, it is marketed in more than 20 countries and regions such as the U.S., Europe, South Korea, etc. (sold by licensing-out companies and sublicensee, Kyowa Hakko Kirin Co., Ltd. etc.). Solasia Pharma is planning potential extension of indication of "Sancuso® (SP-01)" from current CINV (Chemotherapy Induced Nausea and Vomiting) to RINV (Radiotherapy Induced Nausea and Vomiting).
In China, the company finalized their application for approval in June 2014, and obtained approval in July 2018, along with permission to import drug license.
It received milestone payments in the third quarter of FY December 2018, and the sales revenue was recorded.
Thereafter, the manufacturing process for commercial products was established, and manufacturing the products for the first shipment completed. In November 2018, the company began shipping the products to the direct sales destination, ITOCHU Corporation, with which the company entered into a dealership contract for the Chinese market.
Then, the Chinese customs clearance procedures also completed, and sales began as planned in March 2019.
The company conducts sales activities through a self-selling structure in Beijing, Shanghai and Guangzhou, and through Lee's Pharma, which is the licensed distributor, in other regions of China.

Evaluation comments from major Chinese clinicians

On March 16, 2019, the company held (co-sponsored) the " Sancuso® China national launching meeting" in Shanghai.
The chairman of Chinese Society of Clinical Oncology (CSCO), Professor Li Jin, and the vice chairman, Professor Qin Shukui and Professor Ma Jun were chairmen of the meeting, a total of approximately 200 oncologists from all over China attended the meeting. At that meeting, Chinese key opinion leaders made remarks on "SP-01: Sancuso®" as follows.
Professor Qin Shukui (Vice Chairman of CSCO)
"Without any anti-emetic measures, 70%-80% of chemotherapy patients would experience CINV which would severely affect their quality of life. Often, patients will have to be treated with reduced dosage or even withdrawn from chemotherapy, with negative impacts on the treatment outcomes. The traditional CINV prevention methods are mainly short-term intravenous injection, which due to great fluctuation in blood concentration, requires repeated administration which is inconvenient for patients. With unique transdermal system, Sancuso® gradually releases granisetron into blood every day for up to 7days. With one patch per one chemotherapy cycle, it is a new non-invasive treatment choice for chemotherapy patients."

Professor Ma Jun (Vice Chairman of CSCO)
"The emetic risk in patients receiving HEC and MEC chemotherapy will continue for 2-3 days after last dose of chemotherapy. For multi-day chemotherapy, there is an overlap between acute and delayed vomiting, which requires more stable and long-lasting drug. Sancuso® covers different emetic stages including expected, acute and delayed nausea and vomiting. The 7days stable efficacy makes the whole process CINV management possible and allows patients to feel at ease throughout the entire chemotherapy cycle. "

Professor Li Jin (Chairman of CSCO)
"The successful launching of Sancuso provides a long-lasting, stable and non-invasive new choice for the prevention of nausea and vomiting in Chinese chemotherapy patients. As a new choice for the prevention and treatment of chemotherapy related vomiting, with one patch, which is simple and easy, it makes CINV whole process management more convenient, it helps to standardize clinical treatment of CINV and further improves the treatment rate of CINV."

CSCO's first guideline for proper use of antiemetics was issued.

In June 2019, three months after Sancuso® (SP-01) was launched, CSCO issued the first guideline for proper use of antiemetics, and it was listed as a standard antiemetic treatment option for cancer treatment.
Prof. Qin Shukui, deputy director of CSCO and Guideline team leader, said, "This guideline recommends Sancuso® for an antiemetic treatment against highly and moderately emetogenic chemotherapy, providing a non-invasive and tolerable treatment option to cancer patients."

The company plans to grow 6% on the basis of quantity and aims to increase share in China's 5-HT3 RA antiemetic market, which is said to be 80 billion yen or more, through upper and lower streams of sales activities, including gaining recognition from the leading clinicians called Key Opinion Leaders on the characteristics of "Sancuso® (SP-01)" and its advantage over competitors and providing the information to clinicians.

2) "SP-02：novel chemotherapeutic agent darinaparsin"

Item	Overview
Indication	Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL)
Characteristics/Strength compared with competitive drugs	* There are no approved drugs for PTCL indication in Europe (3 drugs on the market in Japan and America). * Compared to the drugs approved in Japan and America, no severe side effect (myelosuppression, stomatitis) has been reported, which means that "SP-02" is highly safe and can be expected for a longer period of time of administration or co-administration.

(Overview of indications)

Malignant lymphoma is one type of hematologic cancer where lymphocytes in white blood cells become cancerous.
The types of lymphocytes include B cells, T cells, and NK cells, and when these cells become cancerous and continues uncontrolled growth, malignant lymphoma develops.

Peripheral T-cell lymphoma (PTCL) is one kind of malignant lymphoma which arises from T cells in lymphocytes and is categorized into the "intermediate-grade lymphoma" where the disease progresses monthly, and it is said to account for 10 - 15% of the intermediate-grade lymphoma. The five-year survival rate from malignant lymphoma is lower than that from B-cell lymphoma, with the ratio being around 25%.

(Current situation of development and commercialization)

The development of " darinaparsin (SP-02)" started aiming for recurring/intractable peripheral T-cell lymphoma (PTCL) indication as mentioned above. There are already results showed that injections were administered to 187 subjects in the U.S., Japan and Korea by October 2015.

The early second phase clinical trials in the U.S. were completed in April, 2012 and have shown certain efficacy in Caucasians.
In the first phase clinical trial completed in April 2015 in Japan and Korea, safety and tolerability of the drug were confirmed, with certain efficacy in Asians suggested.
he international phase II study, which was started in Japan, South Korea, Taiwan, and Hong Kong in 2016 as the final clinical trial, was conducted targeting 65 patients of recurrent or intractable peripheral T-cell lymphoma (as planned), but the enrollment of patients was completed in September 2019.

As initially planned, the trial results after statistical analysis were published in June 2020, achieving the primary endpoint of the "antitumor effect" and identifying no safety concerns in the secondary endpoint. Thus, the company was able to obtain successful results. Based on this, the company plans to apply for approval by the first half of 2021. The test results will be announced in future international academic conferences.
The company is preparing for the final phases II / III of the clinical trials in China. In the U.S., the company completed phase IIA clinical trials. In Europe, the company is in the phase of completing the pre-clinical trials.

Solasia Pharma holds an exclusive worldwide license to develop and commercialize "darinaparsin (SP-02)." For the Japanese market, Solasia has already derived an exclusive right to develop and sell to Meiji Seika Pharma Co., Ltd., and for Republic of Colombia, Peru, Ecuador, Venezuela, Chile, Panama, Costa Rica, and Guatemala, an exclusive right to sell etc. to the Colombian company HB Human BioScience SAS.
Currently, the company is receiving multiple inquiries during the negotiations for licensing agreements targeting regions such as the U.S. and Europe.

It is known that malignant lymphoma often relapses. Accordingly, Solasia Pharma believes that multiple medicines with different mechanisms of action are necessary and the market scale is significant.
In addition, the company is aiming to extend indication of "SP-02" not only to peripheral T-cell lymphoma but also to other hematologic cancers (ATLL (Adult T cell Leukemia / lymphoma), AML (Acute Myeloid Leukemia)) and solid carcinoma and currently, non-clinical trials are being conducted in parallel.
At the 79th Annual Meeting of the Japanese Cancer Association held in October 2020, the possibility that it will become a medicine against adult T-cell leukemia lymphoma (ATL) was suggested.

3) "SP-03：episil® oral liquid"

Item	Overview
Purpose of its use	Control and relief pain of oral mucositis caused by chemotherapy or radiotherapy – Medical Device
Characteristics/Strength compared with competitors	* As there is no standard treatment for stomatitis caused by chemotherapy and radiotherapy, how to relieve the symptom relies on symptomatic treatment by each hospital. There is strong demand for new treatment. * "episil® (SP-03)" contains no pharmaceutical agent, so there is no side effect nor interaction with anticancer agents.

(Overview of indications)
In addition to nausea and vomiting due to anticancer agents, oral mucositis are also serious side effects caused by chemotherapy or radiotherapy.

Stomatitis can be divided into 2 types: the primary stomatitis, which is "stomatitis caused by chemotherapy directly affecting the oral mucosa" or "stomatitis resulted from local infection due to the salivary gland tissue disorder and deterioration of intraoral self-cleansing action because of impaired saliva secretion attributed to radiation exposure" and the secondary stomatitis, which is "attributed to intraoral infection due to myelosuppression resulting from a decline in the number of white blood cells."
The incident rate of stomatitis developing during treatment using anticancer drugs is 30-40%, and that of stomatitis developing during anticancer drug treatment provided together with radiotherapy to the head and neck is nearly 100%.
Stomatitis occurs together with 300-500 inflammations arising in the course of chemotherapy or radiotherapy. The pain makes oral intake of food and water by patients difficult, which results in a decrease in physical strength. In case the symptom is severe, it will adversely affect or halt the progress of cancer treatment. Up until now, there is no established standard treatment therefore the majority of hospitals conducted palliative treatment.

(Overview of "episil® (SP-03)")
" Episil® (SP-03)" is a lipid-based liquid, which is dropped and applied on the oral mucosa, which the company has been developing under the category of medical device.

(Source: Solasia Pharma)

In a few minutes after application of a proper dose to the oral mucosa, the liquid absorbs the water in the oral cavity and transforms to a bioadhesive gel which mechanically protects the affected area. The effect of mitigating the pain of stomatitis has been clinically shown to last for about 8 hours.

(Current situation of development and commercialization)
Solasia Pharma submitted an application for approval in Japan in 2016 and obtained an approval of "episil® (SP-03)" as new medical device in Japan by the Ministry of Health, Labour and Welfare on July 6, 2017. In January 2018, "episil® (SP-03)" was approved at the 388th general meeting of the Central Social Insurance Medical Council for being covered by insurance, starting in April 2018. Following reimbursement listing, 7,660 yen per bottle(10ml) as of October in 2019, in May 2018, it was launched by Meiji Seika Pharma, which is the licensee who holds the exclusive sales rights of "episil® (SP-03)" in Japan.
In China, the company applied for approval in May 2016 and obtained the approval to import and sell medical equipment in February 2019. It began sales of the products in July 2019.
The company conducts sales activities in Beijing, Shanghai and Guangzhou, and through Lee's Pharma, which is a licensed distributor, conducts sales activities in other regions of China.

Due to the product characteristics of "episil® (SP-03)," the company will "create a market" instead of entering into the existing market. The market is estimated to be 20 to 30 billion yen in Japan and China, and the company is aiming to acquire a 30-50% market share.

In South Korea, the company concluded a contract for introducing the exclusive right to develop and sell the medical device in South Korea with Camurus AB, which is the licensing-out company, in August 2018, applied for approval to authorities in March 2019, and

acquired the approval for import and sale of medical device in South Korea in October 2019. In January 2020, the company concluded a contract for exclusive dealership with Synex Consulting Ltd. as a sales partner in South Korea.
In September 2020, the sales started as initially planned.

4) "SP-04: Intracellular superoxide scavenger PledOx®"

Item	Overview
Indication	Chemotherapy induced peripheral neuropathy (CIPN)
Characteristics/Strength compared with competitive drugs	* There is currently no approved drug to prevent or treat CIPN. * Superoxide dismutase mimetics to discompose and remove superoxide as one of reactive oxygen substance (ROS)

While steady progress in general was being made in development of the three preceding products, the company, which had been considering in-licensing the fourth pipeline since it became listed, sought for a new drug that satisfies the following three criteria: "it is aimed for the oncology," "certain progress has been made in clinical trials," and "the company can gain the development right both in Japan and in China." Then, in November 2017, the company was granted the exclusive rights to development and commercialization of "PledOx®," a drug for treating CIPN, in Japan, China, South Korea, Taiwan, Hong Kong, and Macau by PledPharma AB (Currently Egetis Therapeutics AB, hereinafter referred to as "PledPharma") of Sweden. Aiming to obtain the approval as early as possible, the company will forge ahead with clinical development in Eastern Asia, such as Japan and China, with an initial focus on peripheral neuropathy caused by administering "oxaliplatin," a typical anticancer drug for treatment of colorectal cancer.

(Overview of indications)
Chemotherapy-induced side effects occur not only nausea and vomiting, and oral mucositis, but also peripheral neuropathy (CIPN). It is known that CIPN is caused pronouncedly by major drugs for chemotherapy, such as platinum- and taxane-containing drugs.
The FOLFOX treatment, which is a typical medical treatment in chemotherapy and adjuvant chemotherapy against advanced and recurrent colorectal cancer (stage III and IV) that is difficult to cure by surgery, uses three drugs, including fluorouracil, folinic acid, and oxaliplatin. About 90% of patients have reported that prescription of oxaliplatin caused CIPN accompanied by the following symptoms: "dysesthesia on hands and feet, parts around the lips, and others," "tightness in the pharynx and larynx accompanied by difficulty in breathing and dysphagia," "numbness of hands and feet," "hypoesthesia," and "sensory ataxia."

If these side effects appear, by suspension of administering the drugs, some of the symptoms are alleviated in 80% of the cases and completely recovered in 6 to 8 months in 40% of the case; however, as discontinuation of administration of the drugs may mean suspension of cancer chemotherapy and change in the treatment policy, treatment of CIPN is one of the crucial medical issues. There is currently no approved drug to prevent or treat CIPN.

(Overview of "PledOx® (SP-04)")
PledPharma, the originator of " PledOx®(SP-04)" is listed on Stockholm Stock Exchange and has strengths in development of pharmaceuticals against oxidative stress-related diseases.
"PledOx®" （active ingredient name：calmangafodipir）is a new active ingredient created based on "Mangafodipir," an MRI contrast medium, which had sold in the United States and Europe.
"PledOx®(SP-04)" is a front-runner in the development of CIPN drugs, and successful development not only leads to significant first-mover benefits, but also makes a significant contribution to society, such as improving the quality of life of cancer patients.

*Marketability
According to Solasia Pharma, the number of colorectal cancer patients who undergo the FOLFOX treatment is estimated to be around 60,000 – 100,000 in Japan and about 200,000 in China per year.
The FOLFOX treatment is made up with a treatment cycle that continues for 14 days in total, including "3 days for medical care and 11 days as a washout period," and patients are required to repeat the cycle 12 times.
Although the indication which the FOLFOX treatment is aimed at is colorectal cancer whose patients receive cancer chemotherapy, including administration of oxaliplatin, it is known that CIPN is caused conspicuously by other major pharmaceuticals used in cancer chemotherapy, such as platinum- and taxane-containing drugs. The company expects that, if other solid cancers than colorectal cancer,

such as breast, lung, ovarian, and pancreatic cancers, are added to the indication, the marketability will become higher.

(Current situation of development and commercialization)

◎ Development status

PledPharma has carried out research and development of PledOx® against CIPN in the United States and Europe and it has been suggested, based on the results of the phase II study and the preceding trials, that PledOx® is effective and safe in advanced colorectal cancer patients who are receiving the FOLFOX treatment; in other words, it improves CIPN and does not influence the cancer treatment using the FOLFOX treatment. Upon consideration of out-licensing "SP-04" to Japan, PledPharma was convinced of the necessity to hold study involving Japanese, therefore, it conducted the phase I study of PledOx® in the United States with Japanese as the subjects. The trial was closed in Feb. 2018, and excellent safety and tolerability of SP-04 in Japanese has been confirmed.

In November 2018, Pled started the international phase III clinical trial after consulting with Food and Drug Administration (FDA) and European Medicines Agency (EMA).
In parallel, Solasia Pharma K.K. consulted with Pharmaceuticals and Medical Devices Agency (PMDA) and decided to participate in the international phase III clinical trial in Japan, South Korea, Taiwan, and Hong Kong, where Solasia Pharma has rights, while avoiding the phase II clinical trial, in June 2018. In December 2018, the company started the clinical trial as a final study.

The trial overview is as follows.

Study description	Phase III, International, multicenter, double-blind, randomized, placebo-controlled study (*)
Purpose of the study	The effect of suppressing the peripheral neuropathy associated with administration of oxaliplatin by PledOx®(SP-04) administration compared with placebo.
Study design	(POLAR-M study) Colorectal cancer patients who undergo mFOLFOX therapy with distant metastases are included. (POLAR-A study) Colorectal cancer patients who undergo mFOLFOX therapy as an adjuvant therapy for postoperative surgery are included.
Primary outcome measures	Both the POLAR-M and POLAR-A studies will include subjects with moderate or higher chronic peripheral neuropathy at 9 months after (first day of FOLFOX therapy) the initial administration of PledOx®(SP-04) is evaluated.
Estimated enrollment	(POLAR-M study) 420 patients (Developed with PledPharma) (POLAR-A study) 280 patients (Developed with PledPharma)

※ Placebo-controlled study. In clinical study for medicine, subjects are divided into a control group and a treatment group, and the control group is given a placebo. A "placebo" resembles the study drug as much as possible, including color, weight, taste and smell, and does not contain pharmaceutical agents.

However, FDA ordered the clinical hold of the POLAR-M study conducted by Pled in January 2020. In response, although Pled suspended the seeking of new subjects and the administration of the investigational new drug in the POLAR-M study in the U.S., Data Safety Monitoring Board, which was established in that study program, had judged that the study could be continued as planned, so Pled and Solasia Pharma conducted the study as planned in Europe and Asia (Belgium, Czech Republic, Germany, Spain, France, the U.K., Hungary, Italy, Japan, South Korea, Taiwan, and Hong Kong) even after the FDA's order in the U.S. in January 2020. In February, ANSM in France ordered the clinical hold.
As multiple authorities ordered the suspension of the study, Pled decided to suspend the seeking of new patients in all regions and the administration of the investigational new drug in regions other than the U.S. and France, too, in order to protect the safety of subjects more carefully.
Since then, the Data Safety Monitoring Board has conducted a new safety assessment, which revealed multiple severe allergic reactions and hypersensitivity after multiple doses of oxaliplatin and SP-04. It was recommended to stop new subject-enrollment and the administration of the investigational drug.

Following this recommendation, Solasia Pharma and Pled made the following decisions:

* Regarding the ongoing global Phase III study, the company will change the initially planned process and conduct an early deadline for collecting case data, "data cut-off" in the third quarter (July-September) of this term and complete global phase III study.
The number of subjects included so far is 590, compared to the originally planned 700 cases.

* Solasia Pharma and Pled will conduct a detailed and robust evaluation of safety and effectiveness, centered on the information obtained at the end of the trial, and formulate a plan for "PledOx® (SP-04)" after that.
Arai, the president of Solasia Pharma, said that ensuring the safety of subjects is the most crucial element in conducting clinical trials. He declared that the company's future policies are as follows:
"The two companies have evaluated the usefulness of "PledOx® (SP-04)" for cancer chemotherapy-induced peripheral neuropathy, based on the vast amount of data obtained so far, and agreed on doing their best to ensure future development and application for approval of "PledOx® (SP-04)". Based on the current evaluation and recommendations of the Data Safety Monitoring Board on allergic reactions, we will continue to make efforts to elucidate the cause and investigate how to deal with allergic reactions that are suspected of increasing the risk due to the combined use of the chemotherapy containing platinum and "PledOx® (SP-04)" to further ensure the safety of future subjects."

Then, on December 15, 2020, the flash report on the global phase III clinical trial was announced.
The major evaluation items regarding efficacy were not achieved. The frequency and details of adverse effects were almost consistent with the expected ones attributable to colorectal cancer, which is the target of chemotherapy and this trial.

*The group concurrently treated with administration of 5 μmol/kg of PledOx® (SP-04) and chemotherapy did not statistically decrease the risk of onset of moderate or serious peripheral neuropathy based on the report of subjects nine months after the first administration cycle of chemotherapy for cancer, compared with the group treated with chemotherapy only (placebo).

*The studied data did not indicate the adverse effects on progression-free survival (PFS), disease-free survival (DFS), and overall survival (OS), which are the indicators of efficacy of the chemotherapeutic agent. The allergic sensitivity pointed out by the Data Safety Monitoring Board at the time of early termination of the test was reported as a serious adverse event in a few subjects, and the augmentation of the risk of onset was observed. The serious allergic sensitivity was observed in the group administered with PledOx® (SP-04) after multiple cycle treatments.
Since the results of this test are limited to the data on major evaluation items, Solasia Pharma K.K. and Pled Pharma AB will evaluate the details of test results regarding secondary evaluation items, etc. and discuss the strategy for developing PledOx® (SP-04).

◎ Expansion of the target range

The company judged that the use of the medicine for peripheral neuropathy induced by cancer chemotherapy other than oxaliplatin would meet unmet medical needs on clinical scenes and contribute to the expansion of the business scale of "PledOx® (SP-04)." In October 2019, the company updated "the contract for introducing PledOx® (SP-04)," which was signed with Pled in November 2017, and agreed with the policy for promoting joint development for expanding the target range.

This update of the contract does not change the regions where Solasia Pharma has rights, that is, Japan, China, South Korea, Taiwan, Hong Kong, and Macau. Among the economic conditions specified in the original contract, the upper limit of the total milestone payment from the company to Pled according to contract money, progress of development, and achievement of certain levels of sales has increased 1.8 billion yen from 9.3 billion yen to 11.1 billion yen, but the royalty rate is unchanged. The increase of revenue, investment in development, and major effects of the change in the economic conditions through the update of the contract are estimated to last long, and do not affect the earnings forecast for this term.

◎ Licensing-out plan

Solasia Pharma plans to give licenses in Japan and other Asian countries. In Japan, it concluded a contract for exclusive distributorship of "PledOx® (SP-04)" in Japan with Maruho Co., Ltd. (Osaka-shi, Osaka) in December 2019.

The economic conditions specified by the contract are (1) Maruho shall pay a lump-sum amount of 1 billion yen to Solasia Pharma, (2) Maruho shall pay up to 18 billion yen as milestone payments to Solasia Pharma according to the progress of development and sale, and (3) Solasia Pharma shall exclusively sell PledOx® (SP-04) to Maruho.

5) "SP-05：arfolitixorin"

Item	Overview
Indication	Increase in antitumor efficacy of the anticancer drug "fluorouracil" (for various cancer treatments, especially for colorectal cancer).
Characteristics/Strength compared with competitive drugs	* Phase I/IIa studies suggested enhanced antitumor effect compared to the standard chemotherapy treatment regimen for colorectal cancer. * Based on the results of the ongoing Phase III study, the company aims arfolitixorin to be added for the colorectal cancer chemotherapy regimen as a "new standard treatment."

In August 2020, as a new pipeline, the company has signed an exclusive in-license agreement with Isofol Medical AB (Sweden) to develop and commercialize arfolitixorin (Solasia Pharma development product code: SP-05, generic name: arfolitixorin) in Japan.
It is estimated that the company will pay a total of up to 10.4 billion yen to Isofol as a payment that includes an upfront payment and milestones according to the development progress and sales achievement after successful development and development investment. Additionally, the company will pay royalties to Isofol according to the proceeds after the starting of sales.

(Overview of "arfolitixorin (SP-05)")
The existing anticancer drug "fluorouracil (5-FU)" is used for various cancer treatments, especially for colorectal cancer. It kills tumor cells by inhibiting DNA synthesis through depleting the chemical substance thymidine necessary for DNA synthesis.
As a standard therapy for colorectal cancer (colon and rectal cancers), "fluorouracil" is often used in combination with the folic acid preparation "levofolinate/folinate," which is used to enhance the antitumor effect of the formulation. However, in that case, a stable effect cannot always be expected since it needs a complex active metabolite conversion.

On the other hand, when "arfolitixorin (SP-05)" was used with "fluorouracil," the action of thymidine shortage was enhanced by administering "arfolitixorin (SP-05)," which is the final active metabolite. Thus, it can be expected that the antitumor effect of "fluorouracil" will be enhanced by combining it with "arfolitixorin (SP-05)" more than when combined with "levofolinate/folinate."

As a result of clinical trials up to phase II conducted by Isofol, it has been suggested that "arfolitixorin (SP-05)" enhances the effectiveness of fluorouracil in patients with advanced colorectal cancer (colon and rectal cancers).
Since it does not require a complex metabolic activation, it can be effective not only in treating all patients with advanced colorectal cancer but patients with pancreatic cancer, small intestinal cancer, breast cancer, gastric cancer, etc., too.

(Overview of Isofol)
Isofol is a Swedish biotechnology company researching and developing the drug arfolitixorin, which aims to enhance the efficacy of standard chemotherapy for advanced colorectal cancer and improve tumor response and progression-free survival period. It has a worldwide exclusive license agreement with one of the big pharmaceutical companies, Merck KGaA, Darmstadt, Germany, to develop and commercialize arfolitixorin's cancer indications. Isofol is listed on the Stockholm Stock Exchange.

(Developmental status)
Since December 2018, Isofol has been conducting phase III studies of "arfolitixorin (SP-05)" in the U.S., Canada, Europe, Australia, and Japan. Solasia Pharma will take over the trials in Japan under this licensing agreement and has been conducting the trials since August 2020.

The target number of cases was set at 440-660 and the company planned to conduct interim analysis with 330 cases. The number of cases reached 330 in July 2020, and 440 in December 2020.
In the interim analysis, the Data Safety Monitoring Board, which was established in this trial, was supposed to determine whether or not this trial should be continued based on the evaluation of safety and efficacy and the number of registered subjects (between 440 to 660

cases) if this trial was to be continued. On March 22, 2021, the Board recommended the company to continue the trial with the minimum number of cases being 440, based on the evaluation of safety and effectiveness in interim analysis (Overall Response Rate (ORR) and Progression-Free Survival (PFS)).

The company considers that this recommendation indicates that there is no sign of toxicity enhancement with SP-05, and by continuing the trial without adding cases to the minimum number of cases set in the clinical trial plan: 440 cases, it is possible to achieve ORR, which is a major item for evaluating efficacy, and PFS, which is a secondary evaluation item.
They expect that by continuing the trial with the minimum number of cases, it is possible to proceed with development in the shortest period of time for the next stage to apply SP-05 to actual treatments.

Solasia Pharma views SP-05 as a vital drug that could further expand the company's innovative cancer treatment portfolio.
More than 150,000 patients are diagnosed annually with colorectal cancer in Japan. The company plans to provide new treatment options for patients with advanced colorectal cancer in Japan through its development partnership with Isofol.
After receiving that recommendation, the company plans to obtain topline results in the first half of 2022, and apply for New Drug Approval to the authorities in the second half of 2022.

1-5 “6 Characteristics” as a Biotech Company

The following 6 points characterize Solasia Pharma as a biotech company:

(1)History of establishment

Solasia Pharma started as “JapanBridge (Ireland) Limited” established jointly by ITOCHU Corporation and MPM Capital, an American VC specializing in bio business, and set up its business by licensing-in new drugs from several biotech companies and propelling development of such drugs.
At first, it mainly considered business transfer to pharmaceutical companies as its exit plan; however, taking account of the business potential and promise, the company shifted its business strategy to persistent business expansion as an independent company and took the path to public stock offering because it was essential to raise funds for research and development. Later, in March 2017, it made a public offering. As the company’s original plan was to sell the company to other companies, the pipelines it owned were comprised of prime assets that could potentially be sold to other companies for encashment even during clinical development. This means that Solasia Pharma has already established a firm business foundation since its inception.

(2) Experienced Clinical development team

Solasia Pharma does not conduct basic research or preclinical trials but in-license assets and specializes in drug creation processes carried out subsequent to the clinical development phase. The most essential thing to achieve in the process of research and development toward commercialization of pharmaceuticals is to eventually obtain approval from the authorities. This requires skills and know-how in the stage of clinical development, especially clinical trials after phase II.
Although there are a number of biotech companies in Japan, CEO Arai stands out with his deep experience and knowledge in clinical development.
The experienced clinical development team, led by CEO Arai, is a significant factor in differentiating Solasia Pharma from other companies and plays a role as a competitive edge.

(3) High rate of successful development

So far, five products including “Sancuso® (SP-01),” “darinaparsin (SP-02)”, “episil® (SP-03)”, “PledOx® (SP-04)”and “arfolitixorin® (SP-05)” were introduced. Three products are commercialized or have reached the final stage towards commercialization.

(Sancuso® (SP-01) was released in China, the application for approval for darinaparsin (SP-02) is in preparation, and episil® (SP-03) was released in Japan, China, and South Korea. As for PledOx® (SP-04), major evaluation items regarding efficacy were not achieved in the flash report on the global phase III clinical trial, and the future development policy is under consideration.)

Such a high rate of successful development is made possible due to the following 2 points: its business model that handles only in-licensed products with a low risk of failure, and its in-house team which can handle all kinds of roles in clinical development. As

mentioned above, the development staff is well aware of what are necessary for obtaining approval and therefore can conduct screening of whether or not an in-licensed product will be approved.
Their so-called “connoisseur (for screening pipelines)” has been realized by the combination of the above 2 strengths, and lowers the risk of abandoning development which is the source of such a high success rate.

Analysis of the cash inflow of a new drug based on the discount cash flow (DCF) model has indicated what comprise of a majority of the total cash inflow is not contract money or milestone income, but royalties which, obviously, will be earned only after successful development of the new drug and expansion of the sales volume.

When making a proposal to Pled Pharma (Sweden), Solasia Pharma did not necessarily have advantages over a number of its competitors in terms of prices, including contract money; nevertheless, it succeeded in in-licensing “PledOx®(SP-04).” The reason behind the success is that PledPharma has thought highly of Solasia Pharma’s capabilities, including the strength of the team for producing distinct clinical trial designs, the results of development of the three preceding products, and the business performance in Asia, including Japan and China, reaching a decision that Solasia Pharma will be the best partner that will bring success in “PledOx®” in Asia.
SP-05 has also been highly acclaimed and introduced as a result of these achievements.

(4) Stable business foundation
Solasia Pharma has successfully conducted licensing-out of the sales rights of the aforementioned 4 pipelines to pharmaceutical companies, which means that in combination with the self-selling system, a portfolio for risk hedge has already been established.

(5) Self-selling system for securing large profit
The reason why pharmaceutical companies have succeeded in securing large profit is that they engage in both manufacturing and selling. At the moment, Solasia Pharma does not own any manufacturing equipment, but the company established a self-selling system to increase profitability in the 3 major cities in China (Beijing, Shanghai, and Guangzhou) which has a large market scale and allows effective sales activities.

(6) Early feasibility of business
Because biotech companies in general post losses in the stage of new drug development, it is not rational to use profit and loss statements for calculating stock prices and enterprise value, and thus the DCF model is used. In case of biotech companies, however, in addition to the discount rate based on “time” which is used in the general DCF model, the success rate for each stage of clinical trials of new drugs is used as another discount rate.
In this case, the most important point is when the company gains approval. Of the five products, “episil® (SP-03)” was already launched in Japan, China and South Korea, and “Sancuso® (SP-01)” was also launched in China, the company has also started preparing to apply for the approval of "darinaparsin (SP-02)." So, the discount rate regarding the company’s development of new drugs should be estimated lower than that of other bio-ventures.
In addition to these six points, the company has high growth potential in the Chinese market.
Understandably, large-scale pharmaceutical companies all over the world have established bases in various Asian countries including China; however, as described in its management policy, Solasia Pharma’s target of development is new products in the field of cancer and rare diseases which major pharmaceutical companies do not enter from the performance-based perspective.
Such products, which nowadays attract high attention, were originally developed by biotech companies, and because major companies do not engage in this area, Solasia Pharma will become an invaluable company that can offer access to the thriving Asian market with its self-selling structure in Beijing, Shanghai, and Guangzhou.
In addition, the company concluded a contract for distributorship in China (excluding Hong Kong and Macau) with ITOCHU Corporation, which excels at the business in China and is the largest shareholder, and can utilize the network of ITOCHU, which is a significant advantage for the company. The largest shareholder signed a new outsourcing agreement in February 2020 to utilize the company's extensive functions to run Solasia Pharma's business.

2. Fiscal Year ended December 2020 Earnings Results

2-1 Overview of consolidated results

	FY 12/ 19	FY 12/ 20	YoY	Initial Estimate
Revenue	1,310	454	-856	500 - 2,000
Gross Profit	1,244	244	-999	-
R&D Expenses	1,138	1,928	+789	1,100 - 1,500
SG&A Expenses	1,868	2,432	+564	2,100
Operating Profit	-1,762	-4,116	-2,353	-2,000 - -2,900
Profit before Tax	-1,797	-4,159	-2,362	-2,000 - -2,900
Net Profit	-1,867	-4,127	-2,259	-2,000 - -2,900

*Unit: million yen. Net profit is profit attributable to owners of the parent.

The sales revenue for FY December 2020 was 454 million yen, down 856 million yen year on year.
It is composed of mainly the product sales of Sancuso® (SP-01) and episil® (SP-03). The sales of the two products were affected by the decrease of visits of medical representatives (MRs) to hospitals and the restrictions on marketing activities and surveys after the release of products due to the novel coronavirus.
The lump-sum revenue from the contract for licensing out SP-04 was posted in the previous term, but in FY December 2020, the negotiation for licensing did not progress due to the restriction on overseas travel.

R&D expenses was 1,928 million yen, up 789 million yen year on year.
This was composed of mainly the clinical development investment and application preparation expenses for the global phase II clinical trial (final test) of darinaparsin (SP-02), the clinical development investment for the global phase III clinical trial (final test) (the allowance for it has been posted partially) of PledOx® (SP-04), and the clinical development investment for the phase-III clinical trial (final test) of arfolitixorin (SP-05) etc.
After receiving the results of the phase III clinical trial of PledOx® (SP-04), the allowance for development expenses was posted, and the expenses exceeded the initial estimate.
SG&A expenses was 2,432 million yen, up 564 million yen year on year. It included costs for marketing, including surveys after the release, costs for operation costs including an in-house operating sales system in China, depreciation and impairment loss (the depreciation of intangible assets for SP-01 and SP-03 and the impairment loss of intangible assets for SP-04). Excluding the impairment loss of SP-04 amounting to 800 million yen, it fell below the initial estimate.
As a result, operating loss augmented 2,353 million yen year on year to 4,116 million yen.

2-2 Financial standing and cash flows

◎Main Balance Sheet

	End of December 2019	End of December 2020		End of December 2019	End of December 2020
Current assets	4,302	3,269	Current liabilities	925	2,079
Cash, etc.	4,116	2,964	Trade payables	800	987
Trade Receivables etc.	10	173	Corporate Bonds	-	1,000
Inventories etc.	3	4	Noncurrent Liabilities	103	43
Noncurrent Assets	3,644	2,506	Total Liabilities	1,029	2,123
Intangible Assets	3,485	2,356	Equity	6,917	3,652
Total Assets	7,946	5,775	Retained Earnings	1,400	-2,726
			Total Liabilities and Net Assets	7,946	5,775

*Unit: million yen. “Cash, etc.” means cash and cash equivalents. “Trade receivables” means trade receivables and other receivables. “Trade payables” mean

trade payables and other payables.

Due to the decreases in cash and deposits, and intangible assets etc., total assets decreased 2,171 million yen from the end of the previous term to 5,775 million yen.
Through the issuance of corporate bonds, total liabilities augmented 1,093 million yen from the end of the previous term to 2,123 million yen.
Due to the decline in retained earnings, total equity dropped 3,264 million yen from the end of the previous term to 3,652 million yen.
Capital-to-asset ratio decreased 23.8% from the end of the previous term to 63.2%.
The amount of the credit line (current account overdraft contract and commitment line contract) under the contract with the domestic banks is 3,500 million yen, all of which are unused.

◎Cash flow

	FY 12/ 19	FY 12/ 20	Increase/Decrease
Operating CF	-828	-2,789	-1,960
Investing CF	-735	-171	+563
Free CF	-1,563	-2,960	-1,397
Financing CF	1,641	1,829	+188
Cash and Cash Equivalents	4,116	2,964	-1,152

*Unit: million yen.

Negative range widened of operating and free cash flow increased due to increased losses. Cash position declined.

2-3 Topics

◎ Announcement of the results of the interim analysis of the phase III clinical trial of arfolitixorin (SP-05)
On March 22, 2021, the company announced the interim analysis results for the phase III clinical trial of arfolitixorin (SP-05).
The Data Safety Monitoring Board recommended the company to continue the trial with the minimum number of cases being 440, based on the evaluation of safety and efficacy in interim analysis.
The company considers that this recommendation indicates that there is no sign of toxicity enhancement with SP-05, and by continuing the trial without adding cases to the minimum number of cases set in the clinical trial plan: 440 cases, it is possible to achieve ORR, which is a major item for evaluating efficacy, and PFS, which is a secondary evaluation item. They expect that by continuing the trial with the minimum number of cases, it is possible to proceed with development in the shortest period for the next stage to apply SP-05 to actual treatments.
After receiving the recommendation, the company plans to obtain topline results in the first half of 2022, and apply for New Drug Approval to the authorities in the second half of 2022.

3. Fiscal Year ending December 2021 Earnings Forecasts

3-1 Full-year earnings forecast

	FY 12/ 20	FY 12/ 21 Est.
Revenue	454	1,600～2,600
R&D Expenses	1,928	1,950
SG&A Expenses	2,432	2,200
Depreciation	1,296	500
Operating Profit	-4,116	-1,800～-2,800
Net Profit	-4,127	-1,800～-2,800
Profit excluding R&D Expenses and Depreciation	-892	650～-350

*Unit: million yen. Net profit is profit attributable to owners of the parent.

Substantial increase in sales forecast, narrowing of loss

The effects of the spread of the novel coronavirus were taken into account when estimating the ranges.
The major assumptions for respective items are as follows.

◎Revenue

The company expects to gain sales revenues from "Sancuso® (SP-01)", and "episil® (SP-03)".
Furthermore, the company expects licensing-out revenue of "darinaparsin (SP-02)" and/or "arfolitixorin (SP-05)" to a certain extent as revenues from product licensing-out.

◎R&D expenses

In addition to the expenses for development of darinaparsin (SP-02) and preparing for applying to the authorities, and the development investment for the phase III clinical trial (final test) of arfolitixorin (SP-05), the development investment for new candidates, etc. will be included.

◎SG&A expenses

It will include the costs for operating systems, including the in-house sales system in China, and marketing costs, including surveys after release.

(Goal as a company)

In addition to achieving the goals for each pipeline, the company is developing a portfolio of multiple items after introducing new items at the appropriate timing for improving pipelines.
Meanwhile, it is also placing importance on the timing of turning the profit and loss excluding R&D expenses into black.

4. Conclusions

In FY December 2020, their business progressed significantly as the company announced positive results of the final clinical trial of darinaparsin (SP-02), introduced the rights for SP-05 and conducted fund procurement for it, and launched episil® (SP-03) in South Korea, but the results of the global phase III clinical trial of PledOx® (SP-04) were not positive unfortunately, as they were not able to satisfy major evaluation items for efficacy and impairment loss was posted.

The outlook for PledOx® (SP-04) is still unclear, but impairment loss has been already posted, and it seems that the stock market is reacting to the following developments. According to the company, famous institutional investors inside and outside Japan, which did not consider the company as an investment target, are increasing their interests in the company.
The operating profit, excluding the R&D expenses and depreciation, for this term is estimated to be at the most, up to 650 million yen, hitting a record high. We are willing to see whether the company will be able to license out darinaparsin (SP-02) and arfolitixorin (SP-05).

＜Reference: Regarding Corporate Governance＞

◎ Organization type and the composition of directors and auditors

Organization type	Company with auditors
Directors	5 directors, including 3 outside ones
Auditors	3 auditors, including 3 outside ones

◎ Corporate Governance Report

Last update date: March 31, 2020

<Basic policy>

We believe that our mission is to contribute to the medical front including patients through our business activities as a drug development company. We also recognize that raising corporate value and returning profits to our shareholders through these business activities and fulfilling our accountability to the stakeholders are important events for achieving our mission. For these reasons, our basic policy is to effectively function corporate governance by securing “compliance” and “transparency” of management, while enhancing the monitoring and supervisory system of external directors and the audit system of corporate auditors.

<Reasons for Non-compliance with the Principles of the Corporate Governance Code (Excerpts)>

Solasia Pharma has stated, “Our company implements all the basic principles stipulated in the Corporate Governance Code.”