President & CEO Yoshihiro Arai

Solasia Pharma K.K. (4597)

Solasia

Company Information

Market	TSE Mothers
Industry	Pharmaceutical products (manufacturing)
President & CEO	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	Number of Shares Issued		Total Market Cap	ROE (Actual)	Trading Unit
¥201	105,022,169 shares		¥21,109 million	-	100 shares
DPS (Est.)	Dividend yield (Est.)	EPS (Est.)	PER (Est.)	BPS (Actual)	PBR (Actual)
¥0.00	-	~~¥-29.65~~	-	¥67.69	3.0 x

*The share price is the closing price on March 22. The number of shares issued, ROE and BPS were the values for the previous term. EPS represents the lower limit of the forecasted range.

Earnings Trends

Fiscal Year	Revenue	Operating Profit	Profit before tax	Profit	EPS	DPS
Dec. 2014 (Actual)	11	-702	-701	-677	-26.90	0.00
Dec. 2015 (Actual)	229	-702	-710	-643	-24.83	0.00
Dec. 2016 (Actual)	501	-462	-494	-474	-18.46	0.00
Dec. 2017 (Actual)	410	-1,009	-1,016	-1,007	-12.24	0.00
Dec. 2018 (Actual)	318	-,2,420	-2,445	-2,422	-25.98	0.00
Dec. 2019 (Forecast)	500 ～1,700	-3,000 ～-2,000	-3,000 ～-2,000	-3,000 ～-2,000	-29.65 ～-19.77	0.00

*The forecast is from the company. IFRS adopted.
*Units: Million yen or yen

This report outlines Solasia Pharma's Fiscal Year December 2018 earnings results, Own Marketing Structures in China and so on.

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Key Points

- **As a specialty pharma* specializing in oncology, Solasia Pharma develops and sells medicine for cancer treatment and supportive care in Asia, mainly Japan and China, which has promising markets. Its significant strengths and features are the experienced clinical development team led by CEO Arai, high rate of successful development, the stable business foundation, early feasibility of business model, and so on.**

- **The sales revenue for FY December 2019 is expected to be in the range of 500 to 1,700 million yen. The company expects revenues from SP-03 (Japan), which was launched in the previous fiscal year, and SP-01 (China) and SP-03 (China), which are scheduled to be launched this fiscal year. In addition, the company expects a certain level of revenues derived from licensing development rights of SP-02 or SP-04, etc.**

- **The business strategy of owning a self-selling system is quite unique in the bio-venture industry, and it is essential to know the outline and progress of the company's own marketing structure in order to determine the possibility of future revenue expansion. The company plans to expand the business in the huge Chinese market with the differentiating factors that are not found in other companies, such as "experienced management team" and "acquisition of a high rating from the Chinese medical community."**

- **The loss in 2019 is likely to mark the record high due to R&D investment and investment in establishing a self-selling system. However, in terms of commercialization, SP-01 in China was launched as planned at the beginning of the fiscal year, acquisition of approval for SP-03 in China and application for approval for SP-03 in Korea have been announced, and SP-03 in China will be also launched in the next six months. It will be a year of a major transformation for the company to evolve from just a "development" stage into a true pharmaceutical company that sells products in a huge Chinese market. What is more notable is the "results of the phase II study, which is the final study of SP-02 in Japan, Korea, Taiwan, and Hong Kong." If the study results are positive, it will open the way for the company to commercialize an anticancer drug for the first time, and this will produce a huge impact that is not comparable to cancer supportive products such as SP-01 and SP-03. Of course, even in that case, it will take at least five years to maximize earnings, but the company will surely receive top-level recognition among many Japanese bio-ventures. We cannot take our eyes off from the company's news in 2019.**

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, which has promising markets.
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

2006	Dec.	ITOCHU Corporation and MPM Capital, an American VC specializing in bio business, jointly established JapanBridge Inc. in the US as a preliminary base for pharmaceutical development projects.
2008	May	Acquired exclusive development and sales rights of the first product "SP-01" in Japan, Taiwan, Singapore, Malaysia, and China (including Hong Kong and Macao) from Strakan International Ltd. (UK). (Furthermore, the rights in Japan were returned to Strakan International Ltd. in January 2011).
2008	Sep.	Changed the corporate name to Solasia Pharma K.K.
2010	Feb.	Out-licensed to Kyowa Hakko Kirin Co., Ltd. exclusive development and sales rights of "SP-01" in Taiwan, Hong Kong, Singapore and Malaysia.
2011	Mar.	Acquired exclusive development and sales rights of "SP-02" in the Asia-Pacific region from ZIOPHARM Oncology, Inc. (USA).
	Dec.	Established a representative office in Beijing for development activities in China.
2013	Jan.	Established an office in Shanghai to prepare for sales activities in China.
2014	Jun.	Applied for new drug application in China for "SP-01."
	Jul.	Acquired exclusive development and sales rights of "SP-02" in the U.S. and Europe from ZIOPHARM Oncology, Inc. (USA).
	Dec.	Established the subsidiary Solasia Medical Information Consulting (Shanghai) Co. Ltd. to provide medical information on the company's products in Shanghai, China.
2015	Jan.	Out-licensed to Meiji Seika Pharma Co., Ltd. exclusive development and sales rights of "SP-02" in Japan.
	Mar.	Acquired exclusive development and sales rights of "SP-03" in Japan and China from Camurus AB (Sweden).
	Nov.	Out-licensed to Lee's Pharmaceutical (HK) Limited exclusive sales rights of the developed product "SP-01" in China (excluding Beijing, Shanghai, Guangzhou, Hong Kong, and Macao).
2016	May	Applied for New Medical Device Application for "SP-03" in China.
	Oct.	Applied for New Medical Device Application for "SP-03" in Japan.
	Nov.	Out-licensed to Meiji Seika Pharma Co., Ltd. exclusive sales rights of "SP-03" in Japan.
2017	Feb.	Out-licensed to Lee's Pharmaceutical (HK) Limited exclusive sales rights of "SP-03" in China (excluding Beijing, Shanghai, and Guangzhou).
	Mar.	Listed on the Tokyo Stock Exchange Mothers (Market of High Growth and Emerging Stocks).
	Jul.	"SP-03" obtained approval for New Medical Device Application in Japan.
	Sep.	Entered into a contract for commercialization by agent of SP-01 and SP-03 in China with ITOCHU Corporation.
	Nov.	Acquired exclusive development and commercialization rights of "SP-04" in Japan, China, South Korea, Taiwan, Hong Kong, and Macau from PledPharma AB (Sweden).
2018	May	Launched episil® (SP-03) in Japan
	Jul.	Obtained approval from Chinese authorities for SP-01: Sancuso®.
	Aug.	Acquired exclusive development and sales rights of SP-03 in South Korea from Camurus AB.
	Aug.	Licensed to HB Human BioScience SAS in Columbia to exclusive commercialization rights of SP-02 in Latin America.
	Nov.	Shipping of "SP-01 Sancuso®" to China began.
2019	Feb.	Obtained approval from Chinese authorities for "SP-03: episil® oral liquid."
	Mar.	Applied for New Medical Device Application for "SP-03: episil® oral liquid" in Korea. Launched "SP-01 Sancuso®" in China.

1-2 Corporate Philosophy/Management Philosophy

The company's name, SOLASIA, is a coined word combining Sol (the Sun in Spanish) 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 existing four 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 preceding, 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.

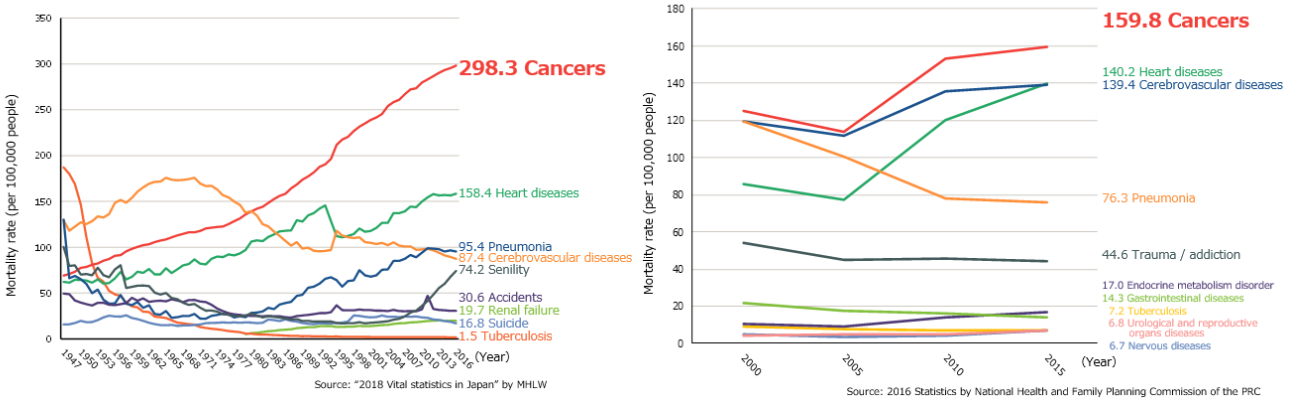
1-3 Environment Surrounding Solasia Pharma

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), 298.3 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.

Currently, the U.S. has the biggest pharmaceutical market, followed by China after it overtook Japan. The global pharmaceutical market grew by about 24% over the past 6 years (2010-2016), but the Chinese market grew by about 113%, 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.

Market Trends - Change in Cancer Mortality Rate, etc.

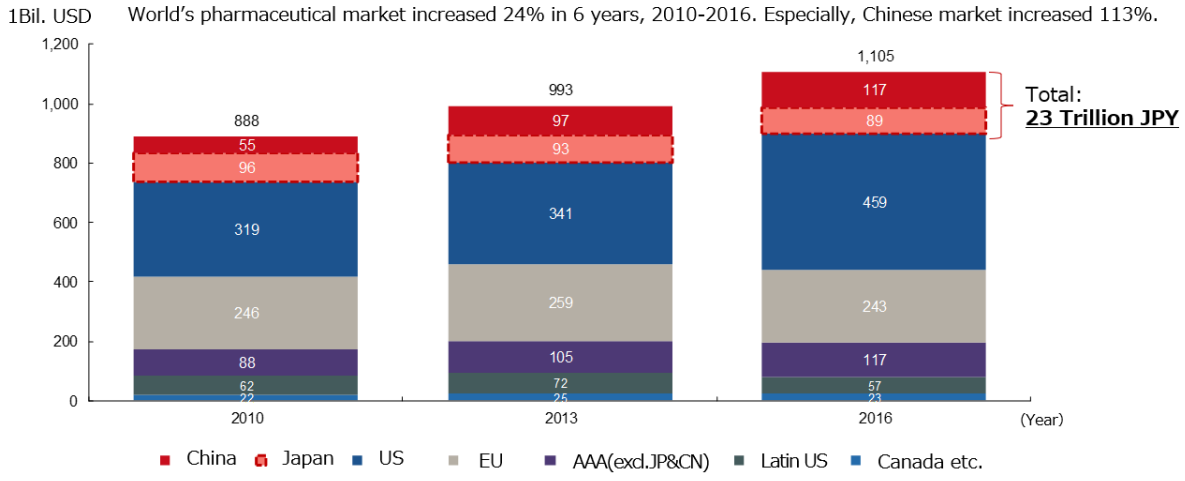


(Source: Solasia Pharma)

World's pharmaceutical market ranking

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

Change in pharmaceutical sales market



※Rate : 1 USD=110.81 JPY
Source : Office of Pharmaceutical Industry Research All Rights Reserved. Copyright©2018IQVIA. World Review Analyst
Source : Solasia created based on "Comprehensive Strategy for Strengthening the Pharmaceutical Industry" by MHLW (Reference Material) and Pharmaceutical Cooperative DATA BOOK 2018

(Source: Solasia Pharma)

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

(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.

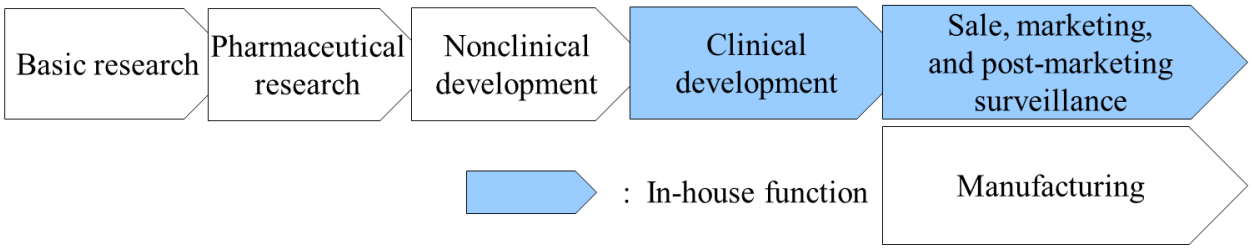
In summary, needs for cancer treatment in Japan and China are growing and there are great expectations for new anticancer drugs and cancer supportive care. Solasia Pharma is establishing business model and business strategy to incorporate such needs and boost earnings.

1-4 Business Description

1-4-1 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 "sale, 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 become 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)

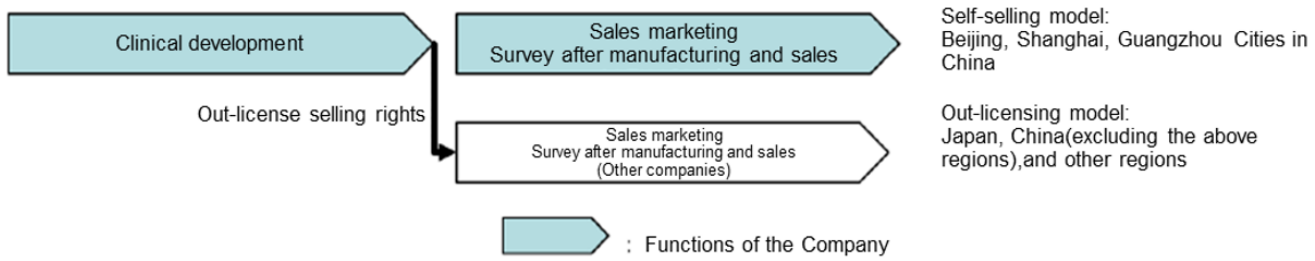
Regarding the sales and marketing structure, the company has set up a system that takes into account the balance between high

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
Takeda Pharmaceutical	1,770,531	1,274,610	72.0%
Astellas Pharma	1,300,316	1,006,066	77.4%
Daiichi Sankyo	960,195	614,173	64.0%

*The values are the results from FY March 2018.
*unit: million yen

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)
Solasia Pharma established its self-selling structure and implemented the self-selling model in 3 major cities in China including "Beijing, Shanghai, and Guangzhou" with maximization of product sales profit and management of fixed cost in mind.

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. Currently, the company is endeavoring to increase the number of sales staff to perform sales activities toward about 50 – 60 large hospitals.

Self-selling activities in China are handled by Solasia Medical Information Consulting (Shanghai) Co. Ltd., which is a wholly owned subsidiary of Solasia Pharma.
Solasia Pharma established its own sales and marketing management team, including 3 business managers, and established bases in Beijing, Shanghai, and Guangzhou.
For the launch of SP-01, which is scheduled to take place in the first quarter of FY December 2019 (already launched on March 18, 2019), the company also established a sales structure managed by about a total of 30 medical representatives (MRs) in three cities.

(Licensing-out model)

The major partners to which Solasia Pharma has currently granted rights include the following 2 companies:

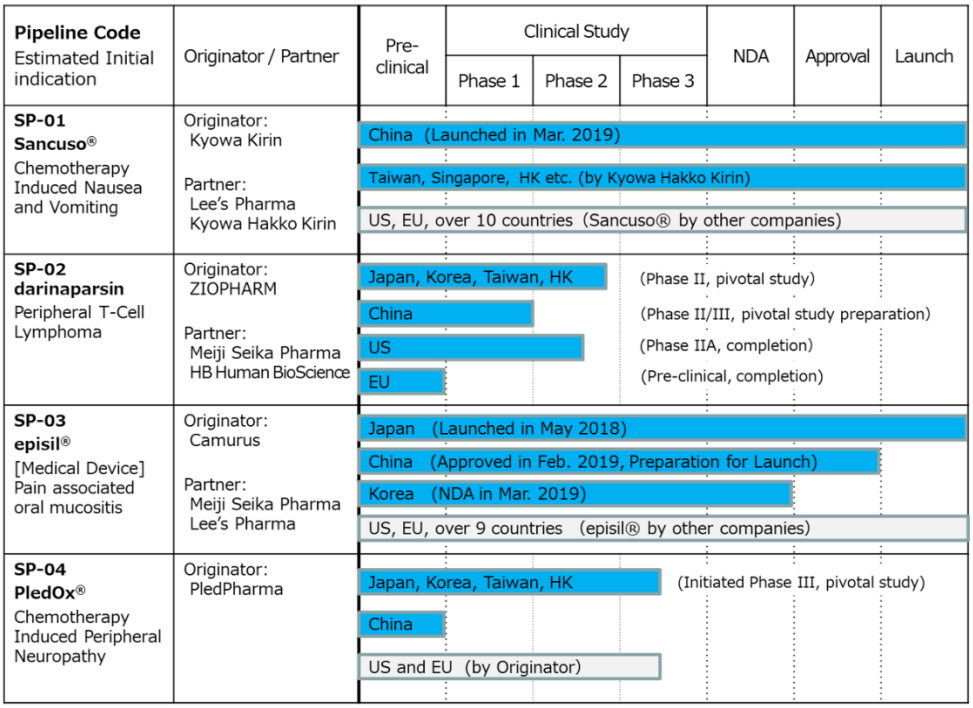
Meiji Seika Pharma Co., Ltd.	・A pharmaceutical company of the Meiji Group, which is a specialty pharma in the fields of cancer, infections, and the central nervous system and has yielded sales results of multifarious products in the cancer field ・A shareholder of Solasia Pharma (which holds 3.6% of Solasia Pharma's shares as of December 2018) ・Japanese partner with the rights of SP-02 Japanese partner with the rights of SP-03
Lee's Pharmaceutical Limited	・A Chinese pharmaceutical company listed on the Hong Kong market, which sells pharmaceuticals for a multitude of fields including the cancer field across China through about 30 bases ・A shareholder of Solasia Pharma (which holds 2.1% of Solasia Pharma's shares as of December 2018) ・Chinese partner with the rights of SP-01 (excluding Beijing, Shanghai, and Guangzhou) Chinese partner with the rights of SP-03 (excluding Beijing, Shanghai, and Guangzhou)

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.

1-4-2 Products/Development Pipeline

Solasia Pharma currently owns the following 4 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 March 2019)



(Source: Solasia Pharma)

1) "SP-01: Sancuso®"

Item	Overview
Indication	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. ・It is already recommended as one of the standards of care for nausea and vomiting in the NCCN* guideline with regard to cancer treatment that is referred to at clinical sites and also in the Chinese version of the NCCN guidelines.

* NCCN: National Comprehensive Cancer Network, which is an organization that formulates guidelines for cancer treatment.

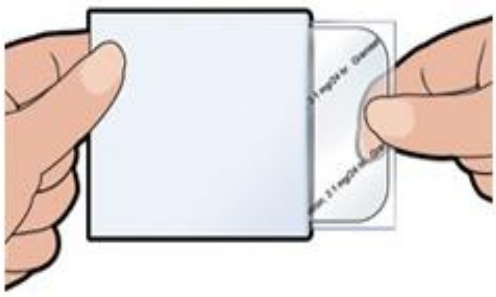
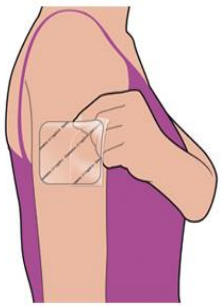
(Overview of indications)

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 "SP-01")

"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, "SP-01" maintains the concentration level of Granisetron in blood on a stable basis for 5 days. Therefore, once a patch of "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, "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)
Development Areas where "SP-01" has currently been launched or approved include America, the United Kingdom, Germany, Italy, the Netherlands, Denmark, Finland, Norway, Sweden, Kuwait, Lebanon, Qatar, Bahrain, the United Arab Emirates, Saudi Arabia, South Korea, the Philippines (sold by originators and others), as well as Taiwan, Hong Kong, Singapore and Macau(sold by a sublicensee, Kyowa Hakko Kirin Co., Ltd.).

Solasia Pharma is planning potential extension of indication of "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 will conduct 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.

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 CINV1 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 outcomes2. 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 7day 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."

The company aims to increase share in China's 5HT3 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 "SP-01" and its advantage over competitors and providing the information to clinicians.

2) "SP-02 : 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 approved 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 "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.
The Asia global phase II clinical trial, which is to be the final trial, was started in 2016 in Japan, Korea, Taiwan, and Hong Kong and is currently in progress for 65 patients (as planned) with relapsed or refractory peripheral T-cell lymphoma, and the number of registered patients reached about 90% of the estimated enrollment. The trial will close by the end of 2019. If the results are promising, they intend to submit an application for approval to the authorities in 2020.
In China, the phase II clinical trial, which is the final trial, is in preparation.

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 (lymphoma, leukemia) and solid carcinoma and currently, non-clinical trials are being conducted in parallel.

The company has already out-licensed the development and sales rights in Japan to Meiji Seika Pharma, and is discussing to which companies in the United States, Europe, and China it should out-license the rights.

In August 2018, the company out-licensed the exclusive commercialization rights of "SP-02: darinaparsin" in Columbia, Peru, Ecuador, Venezuela, Chile, Panama, Costa Rica and Guatemala to the Colombia-based company HB Human BioScience SAS.
With regard to the rights in Europe, the United States, and China, the company is considering to give licensing based on the timing of both before and after announcement of the results of the Asia global phase II study.

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. ・"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 "SP-03")
"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 8 hours.

(Current situation of development and commercialization)
Solasia Pharma submitted an application for approval in Japan in 2016 and obtained an approval of "SP-03" as new medical device in Japan by the Ministry of Health, Labour and Welfare on July 6, 2017. In January 2018, 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, 7,520 yen per bottle(10ml), in May 2018, it was launched by Meiji Seika Pharma, which is the licensee who holds the exclusive sales rights of "SP-03" in Japan.

Also in China, after submitting an application for approval in May 2016, it obtained the approval for medical device in February 2019.
From now on, the company will conduct sales activities in Beijing, Shanghai and Guangzhou, and through Lee's Pharma, which is a licensed distributor, will conduct sales activities in other regions of China.

As for Korea, in August 2018, the company signed a contract with Camurus AB to which the company granted exclusive development and sales rights in Korea for "SP-03," and in March 2019, it submitted an application for approval to the authorities.

In other regions than Japan/China/Korea, which include the United States, United Kingdom, Germany, Denmark, Norway, Sweden, and France, SP-03 has been sold by other companies and the originator.

4) "SP-04: 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 (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. It is known that peripheral neuropathy 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 peripheral neuropathy 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 peripheral neuropathy is one of the crucial medical issues. There is currently no approved drug to prevent or treat CIPN.

(Overview of "SP-04")
PledPharma, the originator of "SP-04: PledOx®" is listed on Stockholm Stock Exchange and has strengths in development of pharmaceuticals against oxidative stress-related diseases.
"PledOx®" (commonly known as Calmangafodipir) is a new active ingredient created based on "Mangafodipir," an MRI contrast medium, which had sold in the United States and Europe.

As described later, "SP-04 : PledOx®" is a drug for treatment of peripheral neuropathy with the most forward progress as the phase IIb study was completed and the global phase III study has started in December 2018. Success in its development will not only bring considerable first-mover advantage but also make enormous social contributions, such as improvement of cancer patients' quality of life (QOL).

*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 peripheral neuropathy 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)
PledPharma has carried out research and development of PledOx® against peripheral neuropathy 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 peripheral neuropathy 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.
Solasia Pharma is intended to take over subsequent study together with the results of other research and development done by PledPharma; therefore, it will embark on the next phase study in this term based on the results of the phase I study. Although discussion as to pharmacokinetic properties is also included in the objectives of the trial, such properties are currently being analyzed.

Meanwhile, in November 2018, PledPharma has started the global phase III study after consulting with the Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Solasia Pharma, which completed the phase I study targeting Japanese, was considering participating into the global phase III study, avoiding the phase II study. Based on the consultation with the Pharmaceuticals and Medical Devices Agency (PMDA) in June 2018, it decided to participate in the global phase III study in countries and regions where the company has the right, namely Japan, Korea, Taiwan and Hong Kong, and began the study, which will be the final clinical trial, in December 2018.

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® 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® is evaluated.
Estimated enrollment	(POLAR-M study) 420 patients (of which 120 patients in own region) (POLAR-A study) 280 patients (of which 80 patients in own region)

※ 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 test drug as much as possible, including color, weight, taste and smell, and does not contain pharmaceutical agents.

With the start of the global phase III study, which is the final clinical trial, commercialization of "SP-04" will move forward. Solasia Pharma plans to conduct clinical trials in China in the future. It also aims to obtain licensing in Japan and Asia.

1-5 "6 Characteristics" as a Biotech Company

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

1-5-1 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.

1-5-2 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.

1-5-3 High rate of successful development

Prior to the latest "SP-04," Solasia Pharma has introduced 3 pipelines including "SP-01," "SP-02" and "SP-03" without suspending or failing at any development process, and all of the 3 pipelines have reached the final stage towards commercialization (SP-01 was launched in China, SP-02 is in the middle of the final clinical trial, and SP-03 was launched in Japan and was approved for sale in China).

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 PledPharma, 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 "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.

1-5-4 Stable business foundation

Solasia Pharma, as mentioned above, has successfully conducted licensing-out of the sales rights of all of the aforementioned 3 pipelines to pharmaceutical companies, which means that in combination with the self-selling system, a portfolio for risk hedge has already been established.

1-5-5 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.

1-5-6 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 four products, "SP-03" was already launched in Japan and "SP-01" was also launched in China, and 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 the above 6 points, the high potential for growth in the Chinese market, too, is one of the characteristics of Solasia Pharma.

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. What is more, the company has entered into a contract for sales by agent in China, excluding Hong Kong and Macau, with ITOCHU Corporation, the largest shareholder that has strengths in business in China. This contract conclusion has offered Solasia Pharma an enormous advantage, that is, it can use ITOCHU Corporation's network.

2. Fiscal Year December 2018 Earnings Results

2-1 Overview of consolidated results

	FY Dec. 17	FY Dec. 18	YoY	Forecasts
Revenue	410	318	-92	100 ～600
Gross profit	410	105	-305	-
R&D expenses	773	1,463	+690	1,300 ～1,450
SG&A expenses	647	1,061	+414	1,800 ～1,900
Operating profit	-1,009	-2,420	-1,411	-3,200 ～-3,000
Profit before tax	-1,016	-2,445	-1,429	-3,200 ～-3,000
Profit	-1,007	-2,422	-1,415	-3,200 ～-3,000

*unit: million yen

Revenue decreased 92 million yen year-on-year to 318 million yen. Revenue consists of sale of SP-03 in Japan, milestone income from Lee's Pharma, and sales of products in China after approval for SP-01.
R&D expenses include the cost of the global phase II study (final clinical trial) for SP-02, and the cost of the global phase III study (final clinical trial) for SP-04. SG&A expenses include the cost of marketing activities in China to prepare for the launch of SP-01 and SP-03, the cost of establishing the sales system in China, and the amortization of intangible assets initiated by the internal system development and business progress of SP-03 and SP-01.

(Recording of costs of assets with capital values as intangible assets and amortization)
Among investments in the pipelines, development costs, etc. of 185 million yen, which are recognized as assets with capital values, was recorded as an increase in intangible assets. The investment in the pipelines in the previous fiscal year was a total of 1,649 million yen, consisting of 185 million yen in intangible assets and 1,463 million yen in R&D expenses.
In addition, amortization of the Japanese business intangible asset of SP-03 began after the product was launched, and amortization of intangible asset of SP-01 began after the company started taking order upon approval from the authorities. Amortization expenses of 148 million yen were incurred in the previous year.

(Difference with forecast)
Although sales revenue exceeded the lower limit (100 million yen) of the forecast due to the launch of SP-01, it fell below the upper limit (600 million yen) of the forecast due to delay in the approval for SP-01 and SP-03 in China. It should be noted that SP-01 was already approved in July 2018. In addition, SP-03 was launched in Japan in May 2018. Meanwhile, in China,

examination of SP-03 by a subordinate body of the authorities was completed, and it was submitted to a higher body for approval (the company obtained the approval in February 2019).
R&D expenses and SG&A fell below the forecast mainly because the global phase II study (final clinical trial) of SP-02 is behind the schedule and is expected to complete in 2019 as well as establishment of a self-selling structure in China upon approval for SP-01 from the Chinese authorities is behind the schedule and is expected to complete in the first quarter of 2019. As a result, the loss amount at each stage was smaller than the upper limit of the business forecast

2-2 Financial standing and cash flows

◎Major BS

	End of Dec. 2017	End of Dec. 2018		End of Dec. 2017	End of Dec. 2018
Current assets	3,525	4,504	Current liabilities	411	619
Cash, etc.	3,370	4,046	Trade payables	372	580
Trade receivables	18	193	Noncurrent liabilities	34	21
Inventories	93	122	Total liabilities	446	641
Noncurrent assets	3,129	3,224	Equity	6,208	7,087
Property, plant and equipment	0	58	Retained earnings	-5,553	-7,975
Intangible assets	3,085	3,123	Total liabilities and net assets	6,655	7,728
Total assets	6,655	7,728	Bank Financing Limit	2,600	3,500

*"Cash, etc." means cash and cash equivalents. "Trade receivables" means trade receivables and other receivables. "Trade payables" mean trade payables and other payables.
*unit: million yen

Cash and capital increased due to public offering. Inventories increased due to preparing for the launch of SP-01 in China. Total assets increased 1,073 million yen from the end of the previous term to 7,728 million yen. Equity ratio (attributable to owners of the parent company) was 91.7%.

◎ Cash Flow

	FY Dec. 17	FY Dec. 18	Increase/decrease
Operating CF	-911	-2,323	-1,412
Investing CF	-537	-256	+281
Free CF	-1,448	-2,579	-1,131
Financing CF	3,781	3,260	-521
Cash and equivalents	3,370	4,046	+676

*unit: million yen

The cash position raised 676 million yen, year on year.

3. Fiscal Year December 2019 Earnings Forecasts

3-1 Full-year earnings forecast

	FY Dec. 18	FY Dec. 19 (Forecasts)
Revenue	318	500～1,700
Cost of sales	213	200～300
Gross profit	105	-
R&D expenses	1,463	1,500
SG&A expenses	1,061	1,800～1,900
Operating profit	-2,420	-2,000～-3,000
Profit before tax	-2,445	-2,000～-3,000
Profit	-2,422	-2,000～-3,000

*unit: million yen

Sales revenue will increase thanks to sales of SP-01 and SP-03. Losses tend to expand due to expansion of upfront investment. As for sales, the market penetration speed is not clear as each product is just launched. As for costs, the timing of starting and closing clinical trials are not clear. Since it is difficult to determine the earnings forecast for the term ending Dec. 2019, the company has announced the earnings forecast with ranges.

(Revenue)
The company expects to gain sales revenues from SP-03 (Japan), which was launched in FY December 2018, SP-01 (China), which was launched during the current fiscal year, and SP-03 (China), which will be launched during the current fiscal year. However, it anticipates that market penetration at the initial stage of sales will be limited relative to the assumed business scale. In addition, a certain level of revenues will be generated from the sales licensing of SP-02 or SP-04 etc.

＊Case in which sales revenues is 500 million yen (the lower limit of forecast).
Sales are expected to be 50% each for SP-01 and SP-03.

＊Case in which sales revenues is 1,700 million yen (the upper limit of forecast).
A portion of the revenues derived from the sales licensing of SP-02 or SP-04 is expected to be around 500 million yen.
Sales of SP-01 and SP-03 are estimated to be 600 million yen, respectively.
The keys to the growth in sales in Japan include progress with collaboration with the medical and dental fields and enhancing recognition of the products.

(Operating costs)
The following items are mainly recorded.

- Cost of sales from the sales of SP-01 and SP-03.
- Investments in management of the self-selling system for SP-01 and SP-03 in China and marketing activities including post-marketing surveys.
- Investment in the phase II study that will be the final clinical trial for SP-02 and investment in the phase III study that will be the final clinical trial for SP-04.
- Amortization expense for intangible assets will be incurred in the full year following the launch of SP-01 and SP-03. However, the amortization expense corresponds to the expenditure of the previous fiscal year, and thus, there is no expenditure in FY December 2019.

(Operating profit or loss)
It is expected that losses of 2 to 3 billion yen will occur at each stage, as the company continues to make upfront investments.

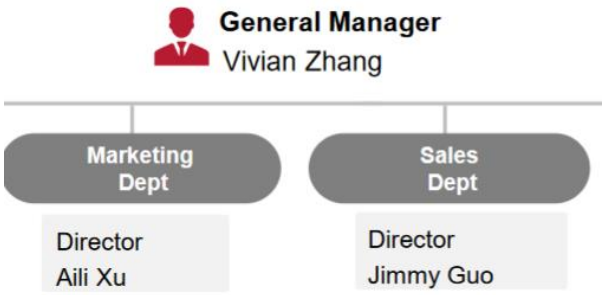
Operating loss excluding R&D expenses is estimated to be 500 to 1,500 million yen.

(Goal as a company)
In addition to achieving the goals of each pipeline, the company is promoting the introduction of newly developed products to strengthen the pipelines.
In addition, as a numerical target, it is aiming to achieve profitability of operating profit excluding R&D expenses in early stage after 2020. Meanwhile, it is also placing importance on the timing of turning the profit and loss excluding amortization expenses into black.

4. Own Marketing Structures in China

One of the features of the company is to operate a self-selling system in three major cities in China, namely, "Beijing, Shanghai and Guangzhou." It is quite unique for a bio-venture company to own a self-selling system. It is essential to know the outline and progress of the company's own marketing structure in order to determine the possibility of future revenue expansion through maximization of product sales profit and management of fixed expenses.

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 3 people in charge.



(Source: Solasia Pharma)

Position	Name	Background
General Manager	Vivian Zhang	Former Roche, Director of the Chinese Cancer Field Business, etc., Physician (former Shanghai Ninth People's Hospital)
Marketing Director	Aili Xu	Former Roche, BMS, Sanofi, etc. Physician (former Shanghai General Hospital, Emergency Room)
Sales Director	Jimmy Guo	Former Roche, BI, etc. Physician (former Sozhou Municipal Hospital Cardiac Surgery)

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.
Furthermore, Dr. Aili Xu and Dr. Jimmy Guo are both former clinicians and have extensive marketing and sales experience at Roche.

Under these 3 experts, the company employed a total of 24 MRs for the sales of SP-01 at present (February 13), including 9 MRs in Shanghai, 8 MRs in Beijing, and 7 MRs in Guangzhou. 70% of them are from major foreign-owned pharmaceutical companies and have an average of more than two years of sales experience in the oncology field.
The company operates a strong marketing and sales force under an experienced management team composed of people who had worked at Roche.

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, 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 often referenced in the clinical setting.
In addition, as mentioned above, at Chinese Society of Clinical Oncology (CSCO), prominent clinicians who are leading the field of cancer treatment in China highly valued SP-01 for its feature of easily suppressing nausea and vomiting in the entire chemotherapy process.
The company is receiving such a high rating because of the superior efficacy of 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
As mentioned above, in order to sell SP-01, the company has already established an operation system with a total of around 30 MRs in 3 cities in China.
In these cities, the company will cover mainly 69 large hospitals where influential physicians work and promote sales expansion by diffusing information from there.
In addition, it is planning to further increase MRs when it launches SP-03, which is expected to happen in 2019.

5. Conclusion

The loss in 2019 is likely to mark the record high due to R&D investment and investment in establishing a self-selling system. However, in terms of commercialization, sales of SP-01 in China was started as planned at the beginning of the fiscal year, acquisition of approval for SP-03 in China and application for approval for SP-03 in Korea have been announced, and SP-03 in China will be also launched in the next six months. It will be a year of a major transformation for the company to evolve from just a “development” stage into a true pharmaceutical company that sells products in a huge Chinese market. What is more notable is the “results of the phase II study, which is the final study of SP-02 in Japan, Korea, Taiwan, and Hong Kong.” If the study results are positive, it will open the way for the company to commercialize an anticancer drug for the first time, and this will produce a huge impact that is not comparable to cancer supportive products such as SP-01 and SP-03. Of course, even in that case, it will take at least five years to maximize earnings, but the company will surely receive top-level recognition among many Japanese bio-ventures. We cannot take our eyes off from the company’s news in 2019.

<Reference: Regarding Corporate Governance>

◎ Organization type and the composition of directors and auditors

Organization type	Company with an audit and supervisory board
Directors	6 directors, including 4 outside ones
Auditors	3 auditors, including 3 outside ones

◎ Corporate Governance Report
Last update date: April 2, 2018

<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.”