President Yoshihiro Arai

Solasia Pharma K.K. (4597)

Solasia

Company Information

Market	TSE Growth Market
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
¥30	174,373,910 shares		¥5,231 million	-49.0%	100 shares
DPS Est.	Dividend Yield Est.	EPS Est.	PER Est.	BPS Act.	PBR
¥0.00	-	¥-4.60 ~ -3.16	-	¥10.78	2.8x

*The share price is the closing price on April 3. The figures were taken from the financial statements for the fiscal year ended December 2023.

Earnings Trends

Fiscal Year	Sales	Operating Profit	Ordinary Profit	Net Profit	EPS	DPS
December 2020 Act.	454	-4,116	-4,159	-4,127	-35.16	0.00
December 2021 Act.	559	-2,419	-2,442	-2,478	-19.04	0.00
December 2022 Act.	1,092	-2,470	-2,492	-2,548	-16.77	0.00
December 2023 Act.	617	-1,139	-1,135	-1,112	-6.62	0.00
December 2023 Est.	1,250 ~ 1,500	-800 ~ -550	-800 ~ -550	-800 ~ -550	-4.60 ~ -3.16	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 pipeline development status, financial results for the fiscal year ended December 2023, and future outlook.

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Key Points

- **In the fiscal year ended December 2023, sales revenue was 617 million yen, down 475 million yen from the previous fiscal year. The sales revenue is composed of mainly the sales revenue from "Sancuso® (SP-01)," "DARVIAS® (SP-02)," and "episil® (SP-03)." Regarding "Sancuso® (SP-01)" and "episil® (SP-03)," the shipment volume of products declined from the middle of the year, due to hospital surveys for eradicating corruption in China, etc. The contract for licensing out "DARVIAS® (SP-02) " in China, which was scheduled to be signed in 2023, was not concluded. R&D expenses were 403 million yen, down 480 million yen year on year. The R&D expenses are attributable to mainly the animal testing for "PledOX® (SP-04)," investments in new development candidates, investments for manufacturing site changes to reduce product costs, and considerations for expanding the adaptation of "DARVIAS® (SP-02)." SG&A expenses were 1,073 million yen, down 1,177 million yen year on year. Fixed costs were reduced due to the dissolution of the self-distribution system in China conducted in the third quarter of the previous fiscal year. As a result, operating loss decreased 1,331 million yen year on year to 1,139 million yen.**

- **For the fiscal year ending December 2024, sales revenue is projected to be at least 1,250 million yen, which is the sum of 500 million yen as revenues from sale of "Sancuso® (SP-01)," "episil® (SP-03)," and "DARVIAS® (SP-02)" and 750 million yen as lump-sum revenues from the conclusion of the contract for licensing out "DARVIAS® (SP-02)" in China. The impact of inventory liquidation and other factors related to the relocation of manufacturing sites for "Sancuso® (SP-01)" and "episil® (SP-03)" is expected to continue until the middle of the year. Under the assumption that the company will earn all short-term milestone income from the contract for licensing out "DARVIAS® (SP-02)" in China in 2024, an additional lump-sum payment from the contract is expected to amount to 250 million yen, so the upper limit is assumed to be 1.5 billion yen. As a result, the company is forecast to post an operating loss and other losses ranging from 550 million yen to 800 million yen.**

- **Negotiations with multiple companies for the licensing-out of "DARVIAS® (SP-02)" in China are ongoing, with a decision expected in the third quarter. Furthermore, the initiation of clinical trials in China is scheduled for the second quarter of 2025.**

- **Although the process for relocating the manufacturing sites of "Sancuso® (SP-01)" and "episil® (SP-03)" is progressing smoothly, the rising cost of pharmaceutical raw materials (such as chemical compounds) caused by global inflation is undermining the effect of cost reduction.**

- **The development of the fifth pipeline "arfolitixorin SP-05" was suspended in 2022, but ISOFOL, which is a joint development partner and licensor, announced on March 19, 2024 that after comprehensive analysis and evaluation of data with external experts, as it may be possible to further improve the efficacy of the drug candidate by using an optimized dose regimen. ISOFOL decided to conduct phase-I/II study for optimizing the administration regimen and confirming the effectiveness and safety of the new administration regimen.**

- **"Based on the great medical need and the extensive scientic knowledge base for arfolitixorin, we have not only an opportunity but also a responsibility to patients, shareholders, and society at large to continue the development. We have concluded that the potential of arfolitixorin is best evaluated in new clinical studies and are now working intensively**

to initiate a clinical phase I/II study before the end of the year," says Petter Segelman Lindqvist, CEO of Isofol.

- **The licensing-out of "DARVIAS® (SP-02)" in China was expected in 2023, but unfortunately, they did not make a decision about it. However, it seems that the negotiation with the candidate licensee has progressed significantly, so we would like to expect good news from their press releases in the third quarter (July-September) of the current fiscal year.**

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 Japan Bridge 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 "DARVIAS® (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) and provided Lee's Pharmaceutical (HK) Limited with the exclusive license to sell "Sancuso® (SP-01)" at the time of the conclusion of the contract 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 at the time of the conclusion of the contract 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 May 2018, "episil® (SP-03)" was released in Japan, as the first product released by the company. Next, Sancuso® (SP-01) and episil® (SP-03) were launched in China in 2019, followed by episil® (SP-03) in South Korea in 2020, and DARVIAS® (SP-02) in Japan in August 2022, thus moving from the "development" stage to the "sales and commercialization" stage.

In April 2022, the company got listed on the Growth Market of the Tokyo Stock Exchange in accordance with market reorganization.

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.

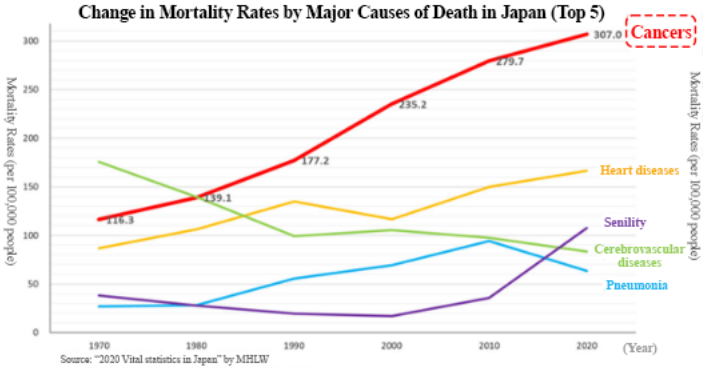
In addition, the following two points are listed as management policy.

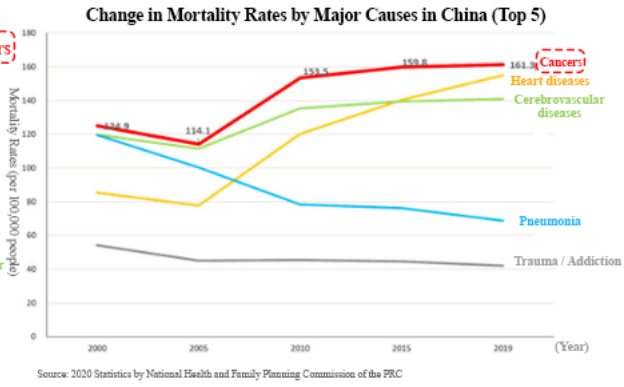
① For the time being, we will continue the in-licensing of new products in cancer and rare disease field where major pharmaceutical companies do not emphasize from a performance-based approach and contribute to patients without adequate medication.
② Through the commercialization of products, we will 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

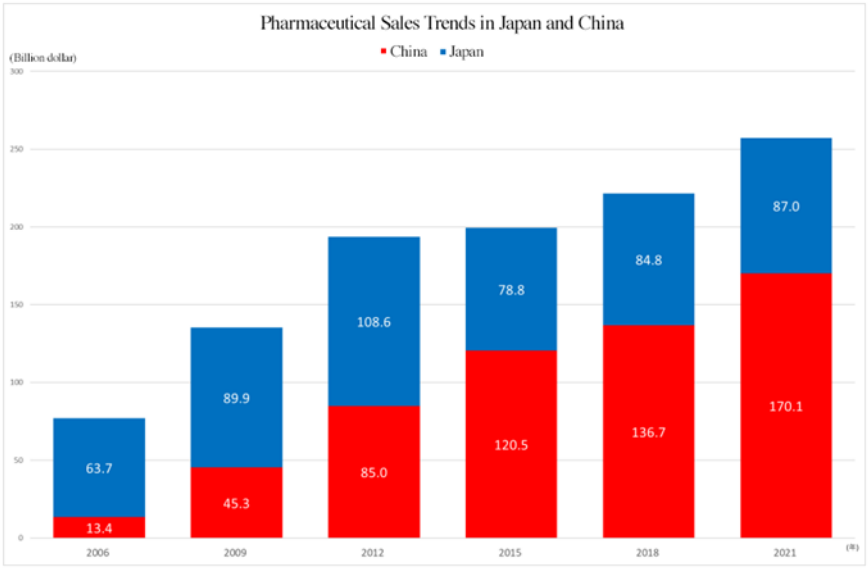
According to "Vital Statistics, 2020" published by the Ministry of Health, Labour and Welfare, in 2020, the leading cause of death was malignant neoplasm (cancer), 307.0 per 100,000 people. In 1981, cancer overtook cerebrovascular diseases, the former number one cause of death, with the mortality rates 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)

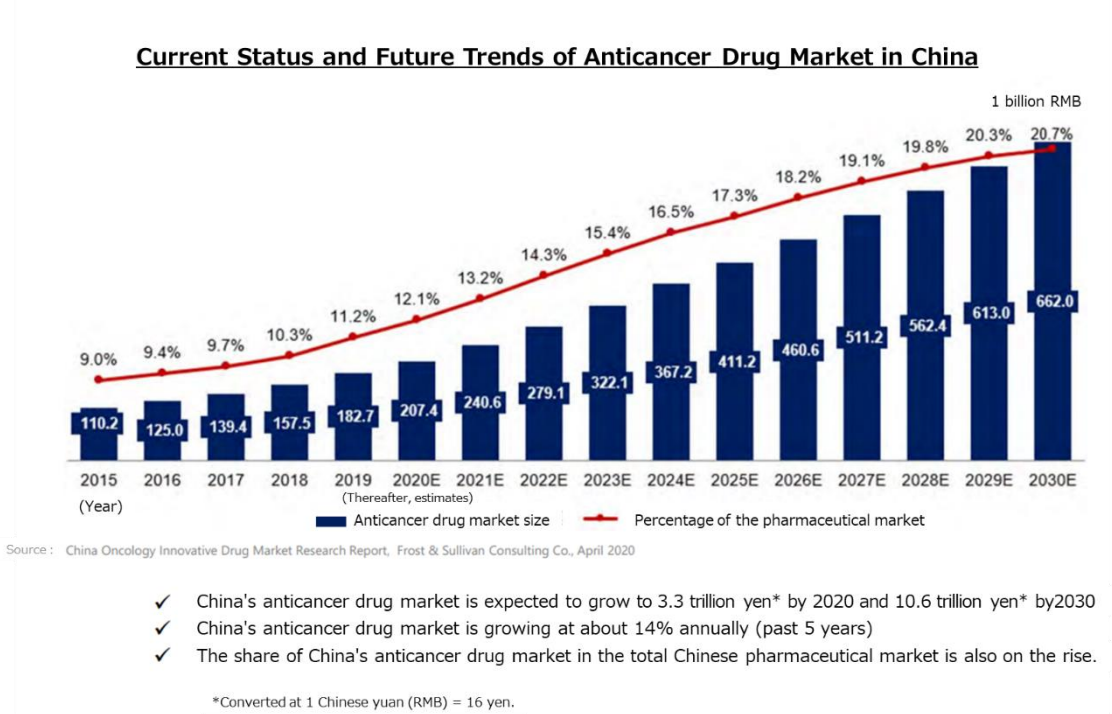
Amid such situation, the sales of the world's pharmaceutical market in 2021 were 1,439.5 billion US dollars (approximately 190 trillion yen). The U.S. has the largest pharmaceutical market, followed by China, which overtook Japan in 2013, and Japan, which has the third largest market.
In the future, 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 257.1 billion dollars (about 34 trillion yen). For the time being, this huge market will be the company's main target.



Source : Japan Pharmaceuticals Manufacturers Association DATABOOK2023
Source : Copyright© 2023 IQMA Made by Investment Bridge based on IQMA World Review from 2006 to 2021 (All rights reserved)

(Source: Solasia Pharma)

In addition, 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.



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.

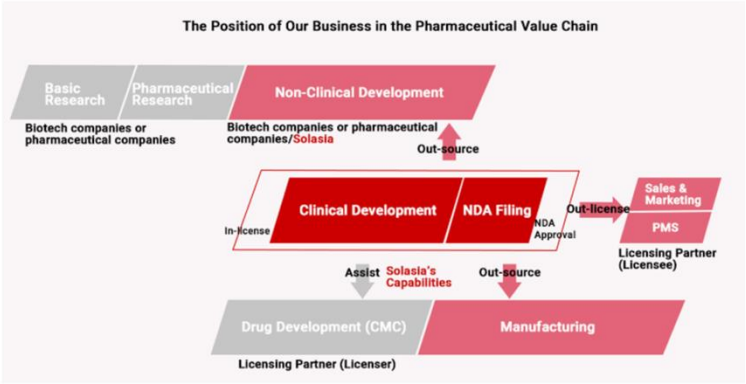
In summary, needs for cancer treatment in Japan and China are growing and there are great expectations for new anticancer drugs and cancer supportive care. Solasia Pharma is establishing business model and business strategy to incorporate such needs and boost earnings.

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 (trials conducted using animals to examine medicinal and pharmacological action, in-vivo pharmacokinetic properties, adverse effects, etc.)," and "clinical development (scientific trials 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 R&D expenses 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 always facing high risks.

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 after 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	1,518,619	1,230,266	81.0%
Daiichi Sankyo	1,278,478	914,952	71.6%

*Unit: million yen. The values are the results from fiscal year ended March 2023.

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 "licensing-out model" (sales rights are granted to other companies for pharmaceuticals that have completed clinical development).

(Self-selling model)
The current major licensing-out partners are the following four 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 "episil® (SP-03)"
Nippon Kayaku Co., Ltd.	*Founded in 1916. The company specializes in cancer-related products in the pharmaceutical business, handles everything from new drugs to biosimilars and generics, and provides medical institutions with highly reliable information necessary for anticancer drugs. *Japanese partner with the rights of DARVIAS® (SP-02)
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.

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, aiming to develop the vast Chinese pharmaceutical market, has entrusted the sales of "Sancuso® (SP-01)" and "episil® (SP-03)" across China to Lee's Pharmaceutical (HK) Limited.

Point: Highly regarded by Chinese medical community

The company abandoned the development of a system for selling products by themselves in China, but their basic conditions for cultivating the huge market in China have not been changed, as mentioned in Section 1-3 "Environment Surrounding Solasia Pharma."

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.

(3) Products/Development Pipeline

Solasia Pharma currently owns the following 4 products/development pipelines in accordance with the above-mentioned management policy. (As of February, 2024)

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.

【Commercial Products】

Product (Development code)	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
Sancuso® (SP-01)	Chemotherapy induced nausea and vomiting (CINV)	China							Launched in 2019 Obtained approval for new manufacturing facility	Lee's Pharm
DARVIAS® (SP-02)	Peripheral T-cell lymphoma (PTCL)	Japan							Launched in August 2022 Began searching for additional indications	Nippon Kayaku (Japan)
	Additional indication under review	South Korea, Taiwan, Hong Kong							Phase II (pivotal) study completed Out-licensing activities ongoing	HB Human BioScience (South America)
		South America							Preparations to file for approval underway in each country based on approval granted in Japan	
		China, US, Europe							Development strategy being drafted based on US study data and approval in Japan; out-licensing activity ongoing	
		overseas countries							NPP strategy being evaluated based on approval in Japan	
episil® oral liquid (SP-03)	Pain associated oral mucositis (medical device)	Japan							Launched in 2018 Preparing to apply for approval of new manufacturing facility	Meiji Seika Pharma
		China							Launched in 2019	Lee's Pharm
		South Korea							Launched in 2020	Synex

Note: For the development status of DARVIAS® in South America, China, US and Europe, are based on past US trials and Japanese approval status.

【Under Development】

Pipeline Code	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, etc.							Pre-clinical study in taxane-induced peripheral neuropathy ongoing* *Pilot study of oxaliplatin-induced peripheral neuropathy completed; results not achieved	Maruho (Japan)

Note: SP-05 has been removed from the above table based on Phase III trial results

【New Drug and Technology Candidates】

GeneCare Project: Aims to treat peritoneal metastasis (peritoneal dissemination) associated with various gastrointestinal cancers, ovarian cancer, etc. and accompanying ascites with the novel nucleic acid drug RECQL1-siRNA.

EditForce Project: Aims to discover gene therapies for cancer using RNA editing that uses the PPR (pentatricopeptide repeat) protein platform technology.

HikariQ Project: Aims to develop innovative immunoassays and discover the next-generation antibody-drug conjugates (ADC), using the novel Q-body technology that embeds fluorescent dyes and drugs inside antibodies.

Goryo Chemical Project: Aims to jointly commercialize navigation drugs for cancer surgery, among others, using functional fluorescent probe technology

(Source: Solasia Pharma)

The development of the fifth pipeline "arfolitixorin SP-05" was suspended in 2022, but ISOFOL, which is a joint development partner and licensor, announced on March 19, 2024 that after comprehensive analysis and evaluation of data with external experts, as it may be possible to further improve the efficacy of the drug candidate by using an optimized dose regimen. ISOFOL decided to conduct phase-I/II study for optimizing the administration regimen and confirming the effectiveness and safety of the new administration regimen.

"Based on the great medical need and the extensive scientic knowledge base for arfolitixorin, we have not only an opportunity but also a responsibility to patients, shareholders, and society at large to continue the development. We have concluded that the potential of arfolitixorin is best evaluated in new clinical studies and are now working intensively to initiate a clinical phase I/II study before the end of the year," says Petter Segelman Lindqvist, CEO of Isofol.

The draft designs of the phase-I/II study is as follows. ISOFOL plans to consult with relevant regulatory authorities.

(Phase-I part)

With a dosage higher than that in the AGENT study and a different administration method (rapid intravenous administration and short-time drip infusion), safety and tolerability will be evaluated with a dose-escalation cohort, and the effectiveness at the early stage will be evaluated. The assumed number of patients is 6-30, although it depends on the results of evaluation of safety of each dose cohort.

(Phase-II part)
There will be about 20 subjects for each of the maximum tolerated dose (MTD) cohort and the second highest dose cohort, which were confirmed in the phase-I study. Preliminary evaluation items are antitumor action, progression-free survival period, and overall survival period as well as an alternative marker for early interpretation.
Interim analysis will be conducted when treatment is completed for half of cases in each group. ISOFOL aims to conduct this study in collaboration with a globally leading academic institution.

At present, ISOFOL is finalizing the details of the clinical trial plan with the aim of submitting the clinical trial plan to regulatory authorities.
If the clinical trial plan is accepted, ISOFOL plans to register the first case by the end of 2024.
By confirming efficacy and safety through this trial, ISOFOL aims to formulate a program for further development of SP-05 and pave the way for commercialization.

For the continuation of the program for developing SP-05, ISOFOL announced that they would cooperate with Merck & Cie, which is an alliance partner for strategic development and manufacturing, and Solasia Pharma, which is an alliance partner for development and commercialization in Japan.

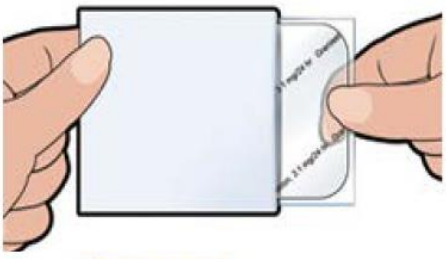
1) "SP-01: Transdermal Delivery System Sancuso®" (Sales name in China: 善可舒®)

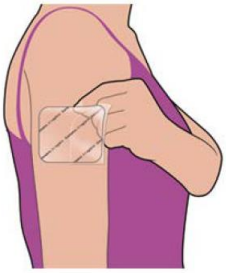
Item	Overview
Efficacy/effect	Chemotherapy Induced Nausea and Vomiting (CINV)
Characteristics/Strength compared with competitive drugs	*The world's only transdermal patch type 5-HT3 receptor antagonist
	*The effect per administration (patch) lasts for 5 days, which covers the administration period of 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 agents 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 has been released (distributed by other companies) in more than 20 countries and regions such as the U.S., Europe, and South Korea, 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. After that, they established a process for manufacturing commercially-available products, and started shipping them to Itochu Corporation, which concluded a distributorship contract in China, but as mentioned above, they dismantled the system for selling products by themselves in Beijing, Shanghai, and Guangzhou on July 31, 2022. Since August 1, Lee's Pharma, which is the licensee, has engaged in sales activities throughout 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 7 days. 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 7 days stable efficacy makes the entire 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 entire 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.

2) "SP-02 : novel chemotherapeutic agent DARVIAS®-"

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 (Other drugs are 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%.
Estimated number of PTCL patients (Japan): Approximately 4,000/year*

(Current situation of development and commercialization)
The development of " DARVIAS® (SP-02)" started aiming for recurring/intractable peripheral T-cell lymphoma (PTCL) indication as mentioned above.

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.
In addition, the international phase II study, which was started in Japan, South Korea, Taiwan, and Hong Kong in was completed in September 2019.

As originally planned, the trial results were announced in June 2020 following statistical analysis. In addition to meeting the requirements for the primary endpoint, which is antitumor effect, no safety concerns were noted regarding secondary endpoints either. As positive results were achieved, the company applied for the approval for manufacturing and sales in Japan in June 2021 for the first time in the world.
On June 20, 2022, DARVIAS®, an anti-cancer agent/organic arsenic preparation, was approved for the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL) by the Japanese Ministry of Health, Labour and Welfare, and was launched on August 22 through its sales partner Nippon Kayaku after being listed in the NHI drug price list (31,962 yen/bottle).

The company is planning to apply for approval in South Korea, Taiwan, and Hong Kong following the conclusion of a contract for offering the sales rights.

In China, they are negotiating for licensing out products under the assumption that the second/third phase clinical test (the final test) will be conducted at the licensee.
In the U.S., the phase-II clinical trial was finished in the previous fiscal year. In Europe, the previous clinical trial was completed, and the phase-II and phase-III clinical trials are in preparation. For both, the negotiation for licensing-out is underway.

Solasia Pharma holds an exclusive worldwide license to develop and commercialize. For the Japanese market, Solasia has already derived an exclusive right to develop and sell to Nippon Kayaku 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. In South America, a marketing authorization application has already been filed in Colombia. In other countries within the region, preparations for authorization applications are underway, based on the approval in Japan.

While licensing out products in China, the U.S., South Korea, etc., they are preparing for selling them in Europe, India, and South America under the Named Patient Program (in which pharmaceutical companies individually supply medicines to medical doctors who want to use the medicines after completing necessary procedures in a country where the medicines have not been approved and their insurance-covered prices have not been determined).
In March 2023, the company started supplying products to mainly Europe via WEP Clinical LTD.

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 to seeking to expand the use of the drug by verifying and proposing synergistic effects when combined with other drugs for peripheral T-cell lymphoma, the company is also aiming to expand the indications to other hematologic cancers (ATLL (adult T-cell leukemia/lymphoma) and AML (acute myeloid leukemia)) and solid tumors, and is currently conducting non-clinical studies 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.
The company will make efforts to increase indications in cooperation with Nippon Kayaku, which is the largest shareholder.

Future growth is expected as it is currently the only anticancer drug whose development has been completed among the pipelines of the company, which engages primarily in the development of anticancer drugs and cancer supportive care (drugs supporting cancer treatment, etc.).

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	*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.

competitors	* “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.
After the application for approval in China in May 2016, the company obtained the approval for import and sale of medical apparatus in February 2019, and started selling products in July 2019, but as mentioned above, the company dismantled the system for selling products by itself in 3 cities at the end of July 2022.
Since August 1, Lee’s Pharma, which is the licensee, has engaged in sales activities throughout China.

In May 2021, episil® (SP-03) was included in the Expert Guidelines on the Diagnosis and Prevention of Acute Oral Mucositis Caused by Antineoplastic Therapy newly published by Chinese Society of Clinical Oncology (CSCO), and recommended as a new treatment

option.
This Guideline is regarded as having "increased the attention of clinical oncologists to oral mucositis and standardized the treatment of oral mucositis in antitumor therapy, which is of great significance," and as episil® (SP-03) was specifically featured, the company anticipates that this will give momentum to sales promotion in China.

In April 2023, episil® (SP-03) was listed as one of the treatment methods for stomatitis in the manual for dealing with serious side effects for each disease, "Stomatitis caused by cancer treatment drugs," published by the Ministry of Health, Labor and Welfare.

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.

In addition, despite a temporary disagreement with Camurus AB regarding product supply, the company acquired worldwide business rights, including manufacturing rights, in July 2022. The business transfer is scheduled to be completed in May 2024.
For the time being, the company will focus on supplying products in Japan, China, and Korea. Solasia Pharma plans to determine its commercialization policy for regions other than Japan, China, and South Korea by the end of the business transfer.
With the acquisition of manufacturing rights, Solasia Pharma has begun evaluating the possibility of reducing product procurement costs by, for example, changing the location of the manufacturing facility from Sweden to Japan and purchasing directly from the manufacturer.

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 Egetis Therapeutics AB (Formerly PledPharma AB, hereinafter referred to as "Egetis") of Sweden.

(Overview of indications)
Chemotherapy-induced side effects occur not only nausea and vomiting, and oral mucositis, but also peripheral neuropathy (CIPN). CIPN is known to manifest considerable symptoms such as dysesthesia in the hands, feet, the area around lips, etc., tightness in the pharynx and larynx accompanied by difficulty in breathing and dysphagia, numbness of the limbs, hypoesthesia, and sensory ataxia, caused by major chemotherapy drugs such as platinum-based drugs and taxanes.
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.
Estimated number of patients (Japan): Approximately 70,000-180,000/year*2 (taxane preparation administration)

(Overview of "PledOx® (SP-04)")
Egetis, 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.

(Current situation of development and commercialization)
◎ **Development status**
The global phase III clinical trial concerning peripheral neuropathy caused by the administration of Oxaliplatin, in which Japan, South Korea, Taiwan, and Hong Kong participated alongside U.S. and European countries, began in December 2018. However, a suspension of the trial was ordered by several authorities as French National Security Agency of Medicines and Health Products (ANSM) issued a clinical hold order in addition to FDA ordering a clinical hold of the POLAR-M study conducted by Egetis in January 2020, etc.
Afterwards, Data Safety Monitoring Board performed a new safety evaluation and recommended the cessation of the registration of new study subjects and administration of the drug used in the clinical trial as multiple cases of severe allergic reactions and hypersensitivity were manifested after repeated administrations of Oxaliplatin and SP-04. As a result, Solasia Pharma and Egetis made changes to the originally planned process, implemented "data cut off" — early closing of the case data collection — in the third quarter (July-September) of 2020, following which it decided to end the global phase III clinical trial.
Moreover, as Solasia Pharma recognizes that securing the safety of study subjects is the most important regarding conducting clinical trials, it declared its policy to formulate the plan concerning PledOx® (SP-04) after performing a detailed and solid evaluation of mainly information obtained after the end of the trial regarding safety and effectiveness.

Then, on December 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.

Since the results of this trials are limited to the data on major evaluation items, Solasia Pharma K.K. and Egetis will evaluate the details of trials results regarding secondary evaluation items, etc. and discuss the strategy for developing PledOx® (SP-04).
Amid such situation, Solasia Pharma has withheld the development concerning Oxaliplatin, which is a platinum-based drug, and is conducting additional animal experiments to explore the possibilities of development aimed at peripheral neuropathy brought about by taxanes.
At this time, while some endpoints defined in the study protocol suggest that PledOx® (SP-04) may have an inhibitory effect on taxane-induced peripheral neuropathy, others do not, and the interpretation of the overall results of the study is complex and has yet to confirm a clear inhibitory effect of PledOx® (SP-04) on the incidence of taxane-induced peripheral neuropathy.

◎ **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 18.0 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.

New development candidates and technologies
In addition to the four pipelines, the development projects of candidate products and technologies that the company is currently focusing on are as follows.
Although they are in the initial stages of research and development, the company is proceeding with initiatives that differ from the conventional "introduction, development, commercialization, or out-licensing" approach.

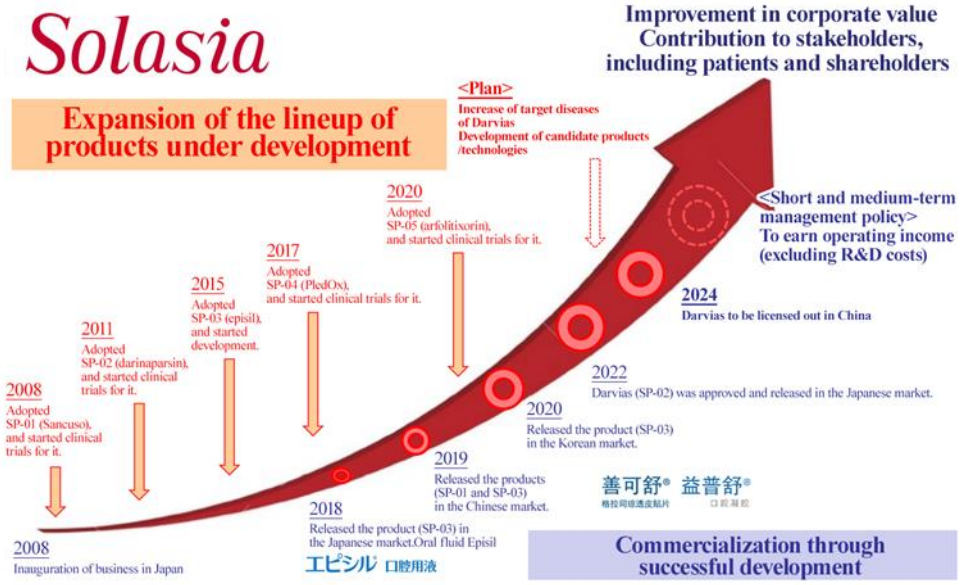
Project	Development Strategy and Background	Features

The nucleic acid medicine RECQL1-siRNA project with GeneCare Research Institute Co., Ltd.	The aim of this project is to develop a nucleic acid medicine for the treatment of peritoneal metastasis caused by gastrointestinal cancer, ovarian cancer, etc. The estimated number of patients with peritoneal metastasis in Japan is around 70,000. The current treatment for peritoneal metastasis primarily involves systemic chemotherapy, which has limited effectiveness and is associated with systemic side effects. Recently, direct intraperitoneal (IP) administration, which is a chemotherapy, has been attempted, but there is no internationally established treatment guideline for peritoneal metastasis according to the Guidelines for Peritoneal Disseminated Disease, and new treatments and medicines are needed. The company has already signed an option contract for licensing out products in this project with GeneCare Research Institute Co., Ltd.	The new active ingredient, RECQL1-siRNA, is a small interfering RNA (siRNA) that targets RECQL1, a DNA repair enzyme helicase family whose overexpression was observed in cancer cells in Japan. It has a new mechanism of action that selectively suppresses the expression of this enzyme in cancer cells, leading to cell death in the M phase of cell division without repairing DNA damage. The basic patent for siRNA is exclusively licensed by Alnylam Pharmaceuticals in the United States. The final formulation is scheduled to be supplied as a lipid nanoparticle (LNP) formulation with a particle size of approximately 100 nm, which is considered optimal for intraperitoneal (IP) therapy, which is a new treatment for peritoneal metastasis.
New RNA editing technology (Pentatricopeptide Repeat: PPR) project with Editforce Inc.	EditForce Inc.'s PPR technology is a gene therapy aimed at definitive treatment through the elimination of disease-causing genes by using exon skipping and knockdown techniques based on PPR technology after selecting diseases for which the causative mutant genes have been identified from various cancers and rare diseases. Currently, multiple diseases and causative mutant genes have been identified, and the conditions for non-clinical studies to verify the anti-tumor effects of designed PPR are being developed.	PR proteins are nucleic acid-binding proteins that specifically bind to RNA base sequences discovered in plants. It is a technology to freely design and construct molecules that bind to target base sequences. They have been reported to have functions such as RNA remodeling ability (unfolding RNA secondary structure), protection from RNA cleavage and degradation, position-specific RNA cleavage, and position-specific base substitution. By elucidating the binding mechanism between PPR proteins and RNA, it is possible to design and construct "artificial nucleic acid-binding proteins that bind to any base sequence" based on it. Unlike the CRISPR-Cas9 genome editing technology, which won the Nobel Prize in Chemistry in 2020, this technology targets RNA.
New Antibody Modification Technology (Quench Antibody: Q-body) Project with HikariQ Co.	Application of next-generation antibody-drug conjugates (ADCs) to drug development. Currently, preliminary evaluation is being conducted on ADC candidates using "Darinaparsin® (SP-02)" as a drug payload.	With HikariQ's Q-body technology, a fluorescent dye is incorporated into the antibody, which is the Q-body, to quench it. When the antibody reacts with the antigen, the incorporated fluorescent dye is released and emits its original fluorescence, and the Q-body functions as a biosensor that

		changes its fluorescence intensity according to the antigen concentration. The immunological measurement technique utilizing this mechanism is expected to significantly simplify and reduce the cost of immunological tests. Moreover, the next-generation ADC drug development is expected to reduce the side effects of anticancer drugs and improve the in-vivo stability of drugs compared to conventional ADCs by applying this technology to pharmaceuticals.

1-5 Envisioned Growth

The company will forge ahead with the sales and development of the above pipelines as planned, work toward commercialization, and achieve a positive operating profit excluding early R&D expenses. In addition, they will keep engaging in new development and continue to grow, aiming to improve the corporate value and contribute to all stakeholders including patients and shareholders.



(Source: Solasia Pharma)

1-6 “5 Characteristics” as a Biotech Company

The following 5 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, four products including "Sancuso® (SP-01)," "DARVIAS® (SP-02)", "episil® (SP-03)" and "PledOx® (SP-04)" were introduced. Three products are commercialized.
(Sancuso® (SP-01) was released in China, DARVIAS® (SP-02) was released in Japan, and episil® (SP-03) was released in Japan, China, and South Korea.

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 Egetis (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 Egetis 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.

(4) Stable business foundation
The company licensed pharmaceutical companies to sell four developed products, establishing a business portfolio in which managerial resources were concentrated on the business from the clinical development stage.

(5) 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 approval can be obtained. Of the five products developed, "episil® (SP-03)" has been launched in Japan, China, and Korea, followed by "Sancuso® (SP-01)" in China, and "DARVIAS® (SP-02)" in Japan. 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 five 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.
These products, which have been attracting attention in the pharmaceutical market in recent years, originate from biotech ventures, but are not handled by major pharmaceutical companies, so the company, which is already highly regarded by the Chinese medical community, will be valuable in providing access to the rapidly growing Asian market for biotech ventures worldwide.

2. Fiscal Year Ended December 2023 Earnings Results

2-1 Overview of consolidated results

	FY 12/22	FY 12/23	YoY
Revenue	1,092	617	-475
Gross Profit	662	337	-325
R&D Expenses	883	403	-480
SG&A Expenses	2,250	1,073	-1,177
Operating Profit	-2,470	-1,139	+1,331
Profit before Tax	-2,492	-1,135	+1,357
Net Profit	-2,548	-1,112	+1,436

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

The sales revenue in the fiscal year ended December 2023 was 617 million yen, down 475 million yen year on year.
It is mainly broken down into product sales revenue from Sancuso® (SP-01), DARVIAS® (SP-02), and episil® (SP-03).

Regarding "Sancuso® (SP-01)" and "episil® (SP-03)," the shipment volume of products declined from the middle of the year, due to hospital surveys for eradicating corruption in China, etc.
The contract for licensing out "DARVIAS® (SP-02) " in China, which was scheduled to be signed in 2023, was not concluded.

R&D expenses were 403 million yen, down 480 million yen year on year.
The R&D expenses are attributable to mainly the animal testing for "PledOX® (SP-04)," investments in new development candidates, investments for manufacturing site changes to reduce product costs, and considerations for expanding the adaptation of "DARVIAS® (SP-02)."

SG&A expenses were 1,073 million yen, down 1,177 million yen year on year. Fixed costs were reduced due to the dissolution of the self-distribution system in China conducted in the third quarter of the previous fiscal year.

As a result, operating loss decreased 1,331 million yen year on year to 1,139 million yen.

2-2 Financial standing and cash flows

◎**Main Balance Sheet**

	End of December 2022	End of December 2023	Increase /Decrease		End of December 2022	End of December 2023	Increase /Decrease
Current assets	1,435	976	-459	Current liabilities	407	293	-114
Cash, etc.	803	728	-75	Trade payables	332	213	-119
Trade Receivables etc.	572	67	-505	Noncurrent Liabilities	64	61	-3
Inventories etc.	14	122	+108	Total Liabilities	472	354	-118

Noncurrent Assets	1,698	1,252	-446	Total Equity	2,662	1,875	-787
Intangible Assets	1,570	1,117	-453	Retained Earnings	-223	-1,336	-1,113
Total Assets	3,134	2,229	-905	Total Liabilities and Equity	3,134	2,229	-905

*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.

While inventory assets increased, a decrease in accounts receivable and intangible assets led to a total asset reduction of 905 million yen to 2.229 billion yen from the end of the previous fiscal year.
Total liabilities decreased 118 million yen to 354 million yen, due to a reduction in trade payables, etc.
An increase in the deficit of retained earnings, among other factors, resulted in a decrease of 787 million yen year on year in net worth to 1,875 million yen.
Capital-to-asset ratio decreased 0.8% from the end of the previous term to 84.1%.

3. Fiscal Year Ending December 2024 Earnings Forecasts and Future Goals

3-1 Consolidated earnings forecast

	FY 12/23	FY 12/24 Est.
Revenue	617	1,250 ~ 1,500
Operating Profit	-1,139	-800 ~ -550
Pretax profit	-1,135	-800 ~ -550
Net Profit	-1,112	-800 ~ -550

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

Sales are expected to grow, decreasing loss.

◎Revenue

Sales revenue is projected to be at least 1,250 million yen, which is the sum of 500 million yen as revenues from sale of “Sancuso® (SP-01),” “episil® (SP-03),” and “DARVIAS® (SP-02)” and 750 million yen as lump-sum revenues from the conclusion of the contract for licensing out “DARVIAS® (SP-02)” in China.
The impact of inventory liquidation and other factors related to the relocation of manufacturing sites for “Sancuso® (SP-01)” and “episil® (SP-03)” is expected to continue until the middle of the year.

Under the assumption that the company will earn all short-term milestone income from the contract for licensing out “DARVIAS® (SP-02)” in China in 2024, an additional lump-sum payment from the contract is expected to amount to 250 million yen, so the upper limit is assumed to be 1.5 billion yen.

◎Operating expenses

For “Sancuso® (SP-01),” “episil® (SP-03),” and “DARVIAS® (SP-02),” it is assumed that the company will incur the cost of sales through the sale of products, invest in clinical development of “DARVIAS® (SP-02)” in China, and post the amortization of intangible assets.
In addition, the company assumes operating expenses due to the investment in development of new drugs, etc. Among them, the amortization of intangible assets is projected to be 160 million yen.

As a result, the company is forecast to post an operating loss and other losses ranging from 550 million yen to 800 million yen.

3-2 Main Business Goals

◎” DARVIAS®（SP-02）”

*Securing revenues through the licensing-out in China

The company is negotiating with multiple companies for licensing-out contracts. They plan to make decisions about licensing-out in the third quarter.

*Preparation for and start of clinical trials in China

They plan to start clinical trials in 2025.

*Narrowing down the target diseases of products

◎” Sancuso®(SP-01)」「episil® (SP-03)”

*Completion of the process for relocating manufacturing sites and implementation of cost reduction measures

The relocation process is progressing smoothly, but the rising cost of pharmaceutical raw materials (chemical compounds, etc.) caused by global inflation is undermining the effect of cost reduction.

*Securing of revenue through the resumption of shipment volume of products from the middle of the year.

◎” PledOx®（SP-04）”

To continue animal testing to check the possibility of clinical development to include "peripheral neuropathy caused by taxane formulations” as an indication.

◎Others

The company will proceed with the investment in research and development for current candidates for development and technologies, including nucleic acid medicines, gene therapy, and the creation of ADC anti-cancer drugs using novel ADC technologies.

4. Conclusions

The licensing-out of “DARVIAS® (SP-02)” in China was expected in 2023, but unfortunately, they did not make a decision about it. However, it seems that the negotiation with the candidate licensee has progressed significantly, so we would like to expect good news from their press releases in the third quarter (July-September) of the current fiscal year.

＜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 23, 2023

<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.”