



President Yoshihiro Arai

Solasia Pharma K.K. (4597)



Company Information

Market	TSE Growth Market
Industry	Pharmaceutical products (manufacturing)
President	Yoshihiro Arai
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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	
¥44	168,472,310 shares	¥7,412 million	-97.1%	100 shares	
DPS Est.	Dividend Yield Est.	EPS Est.	PER Est.	BPS Act.	PBR
¥0.00	-	¥-6.84~-2.08	-	¥13.29	3.3x

*The share price is the closing price on September 5. Share outstanding, DPS, EPS and BPS are taken from the brief financial report for the second quarter of FY December 2023.

Earnings Trends

Fiscal Year	Sales	Operating Profit	Ordinary Profit	Net Profit	EPS	DPS
December 2019 Act.	1,310	-1,762	-1,797	-1,867	-17.75	0.00
December 2020 Act.	454	-4,116	-4,159	-4,127	-35.16	0.00
December 2021 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 Est.	1,000 ~ 1,800	-1,150 ~-350	-1,150 ~-350	-1,150 ~-350	-6.84 ~-2.08	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.

BRIDGE REPORT



This report outlines Solasia Pharma's current pipeline development status and financial results for the second quarter of Fiscal Year ending December 2023.

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Key Points

- The sales revenue in the second quarter of FY December 2023 was 529 million yen, up 340 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). In particular, for Sancuso® (SP-01), the prescription volume was on a recovery trend due to the decline in the impact of the novel coronavirus infection, and shipment quantity increased as sales partners demanded stock increase in preparation for changing manufacturing sites to reduce manufacturing costs. Research and development expenses decreased 155 million yen to 192 million yen. Primarily, the expenses include investments for changing manufacturing facilities to reduce product costs and investments for studying the possibility of expanding the applications of Darvias® (SP-02) and for newly developed product candidates. SG&A expenses decreased 449 million yen to 559 million yen. Fixed costs were reduced due to the dissolution of the self-selling system in China in the third quarter of the previous fiscal year. As a result, operating loss decreased 766 million yen to 462 million yen.
- There are no changes to the full-year earnings forecast. The sales revenue for FY December 2023 is expected to be at least 1 billion yen, by summing up the sales revenues of “Sancuso® (SP-01),” “Episil® (SP-03),” and “DARVIAS® (SP-02),” which was released in Aug. 2022. Considering the possibility of concluding a contract for licensing out “DARVIAS® (SP-02)” in China, it is expected that the sales revenue will be up to 1.8 billion yen, including the additional sales of 0.8 billion yen from the lump-sum payment for the contract. Due to COVID-19, there are significant uncertainties over the sale of products, the possibility of licensing, and the contract amount for licensing. It is assumed that operating expenses will include the cost of sales for “Sancuso® (SP-01),” “Episil® (SP-03),” and “DARVIAS® (SP-02),” the investment in limited marketing activities, including post-release surveys, and 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 450 million yen. As a result, the company is forecast to post an operating loss and other losses ranging from 350 million yen to 1,150 million yen.
- The future of the business of licensing out Darvias® (SP-02) in China remains a major focus. In negotiations with licensees, the deciding factors include economic conditions, future sales volume forecasts and the outlook for the approval process in China. Negotiations are underway with multiple companies. Each company presents its own terms and conditions. Solasia Pharma wants to make a comprehensive decision while focusing on economic conditions.
- The company decided to suspend the development of arfollitoxin SP-05, but in July 2023, ISOFOL, which is the joint developer and licensing company, announced that it is expected to have antitumor effects if the dosage and administration method are changed. It announced the results of the reanalysis of the data from the phase III clinical trial (AGENT trial) and the implementation of non-clinical trials. The results of these non-clinical trials are scheduled to be published after the summer of 2023 and are expected to determine whether clinical development can be restarted. Solasia Pharma is closely monitoring and anticipating the results.
- At the end of last year, the situation was difficult with the end of China's self-sales system and the suspension of the development of SP-05. The company has reached bottom and the company has completed a significant reorganization, so the atmosphere within the company is very positive, and that was clear during the interview. The non-clinical trial results for SP-05 are expected to be released before the announcement of financial results for the third quarter, and we look

forward to the company's release in the next threemonths of 2023, along with the out-licensing of Darvias to China.

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 countries). 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.

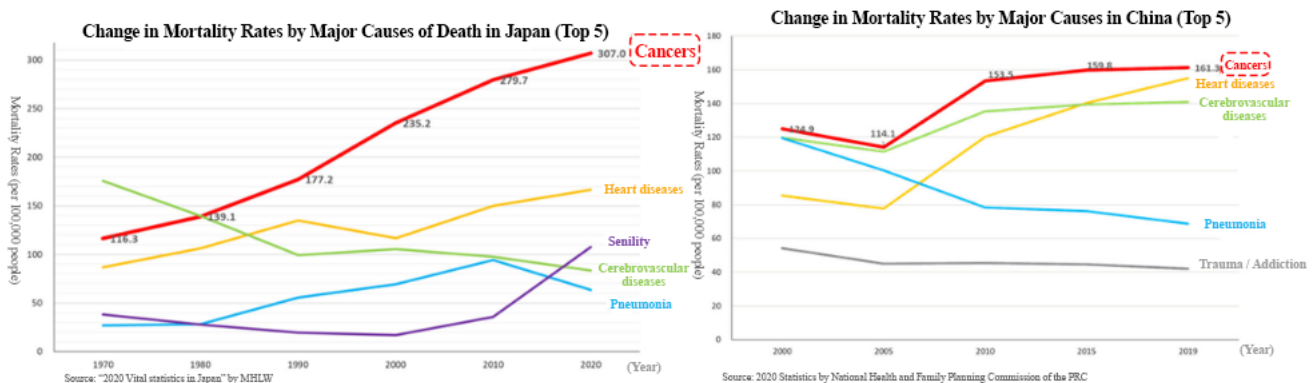
- ① For the time being, we will continue the in-licensing of new products in cancer and rare disease field where major pharmaceutical companies do not emphasize from a performance-based approach and contribute to patients without adequate medication.
- ② Through the commercialization of products, we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

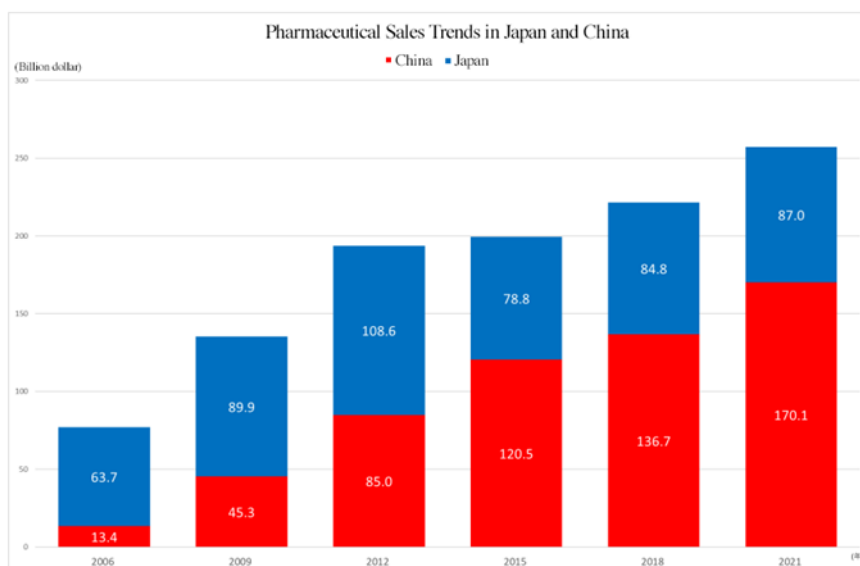


(Source: Solasia Pharma)

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.

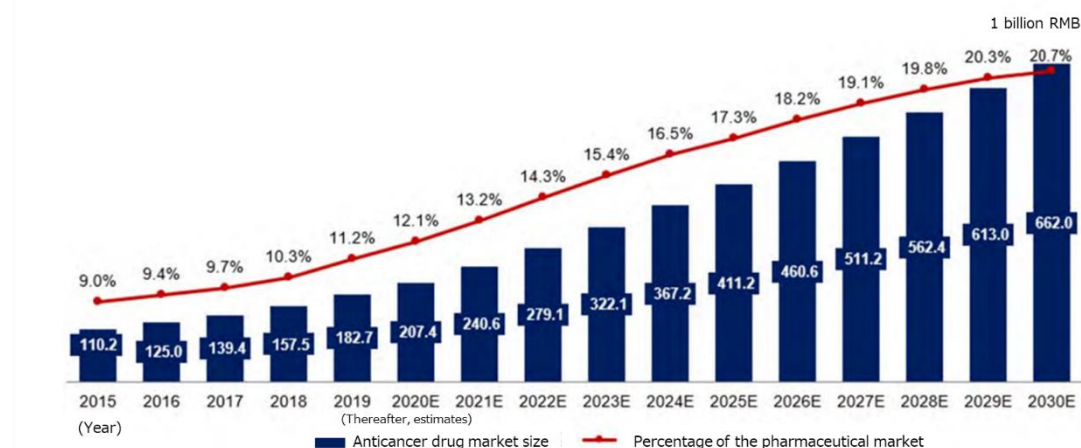


Source : Japan Pharmaceuticals Manufacturers Association DATABOOK2023
Source : Copyright© 2023 IQMA Made by Investment Bridge based on IQMA World Review from 2006 to 2021 (All rights reserved)

(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.

Current Status and Future Trends of Anticancer Drug Market in China



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

- ✓ China's anticancer drug market is expected to grow to 3.3 trillion yen* by 2020 and 10.6 trillion yen* by 2030
- ✓ 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

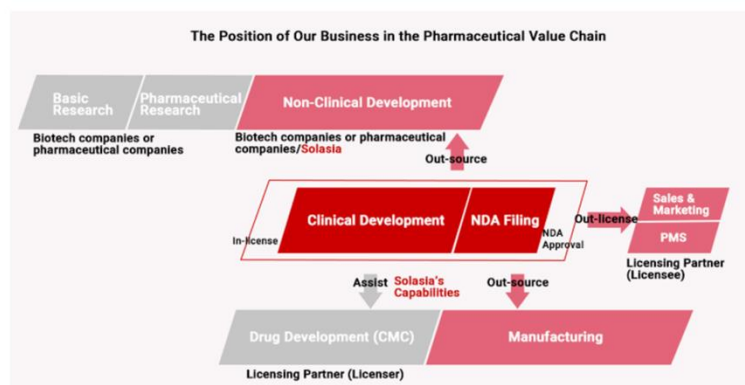
Before the launch of new medicines, it is usual to go through the processes spanning from “basic research” to “pharmaceutical research,” “nonclinical development (trials conducted using animals to examine medicinal and pharmacological action, in-vivo pharmacokinetic properties, adverse effects, etc.),” 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 research and development costs variable, they basically perform all of the above-mentioned processes internally.

Such a system has supported high profitability of pharmaceutical companies. The life science field, however, is currently advancing and becoming complicated and diverse at a rapid rate, and there is an increasing possibility that each company’s unique drug discovery technology quickly becomes obsolete.

In addition, there are a myriad of cases where practical application of new drugs is given up before clinical development, regardless of costs and time spent from the stage of basic research, and therefore new drug is not established in the end. In other words, pharmaceutical development is 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 FY 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.	<p>*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.</p> <p>*Japanese partner with the rights of "episil® (SP-03)"</p>
Nippon Kayaku Co., Ltd.	<p>*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.</p> <p>*Japanese partner with the rights of DARVIAS® (SP-02)</p>
Lee's Pharmaceutical (HK) Limited	<p>*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.</p> <p>*Chinese partner with the rights of "Sancuso® (SP-01)" (excluding Beijing, Shanghai, and Guangzhou)</p> <p>*Chinese partner with the rights of "episil® (SP-03)" (excluding Beijing, Shanghai, and Guangzhou)</p>

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.
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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 cultivate the huge Chinese pharmaceutical market, had initially planned to establish its own sales system in the three major Chinese cities of Beijing, Shanghai, and Guangzhou to maximize profits from product sales and control fixed costs, and develop a self-sales model. However, the impact of the urban lockdown for coping with the spread of COVID-19 was so great that the company decided to abandon the in-house sales model, judging that it would be difficult to achieve its earnings plan as expected.

Lee's Pharmaceutical (HK) Limited will sell Sancuso® (SP-01) and Episil® (SP-03) in Beijing, Shanghai, and Guangzhou.

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 May, 2023)

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			NDA	Approval / Launch	Progress	Partner
				PI	P II	P III				
Sancuso® (SP-01)	Chemotherapy induced nausea and vomiting (CINV)	China							Launched in 2019 Preparing to apply for change of 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)
		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	
		Europe, India							NPP strategy being evaluated based on approval in Japan	WEP(Europe) Sayre (India)
episi® oral liquid (SP-03)	Pain associated oral mucositis (medical device)	Japan							Launched in 2018	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			NDA	Approval / Launch	Progress	Partner
				PI	P II	P III				
SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, etc.							Pre-clinical study in taxane-induced peripheral neuropathy ongoing* *P III 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

(Source: Solasia Pharma)

It was announced that the fifth product in the pipeline, arfolitixorin SP-05, showed no statistically significant improvement in the primary endpoints in the arfolitixorin group compared to the standard therapy group in the preliminary top-line results of phase III of the clinical trials. Therefore, the development was halted, and an impairment loss of 200 million yen on intangible assets was recorded in FY December 2022. However, in July 2023, ISOFOL, the joint developer and licensing company, announced the results of a reanalysis of the data from the phase III clinical trial (AGENT trial), which showed that changes in the dose and the administration method of arfolitixorin were expected to produce antitumor effects, and also announced the implementation of non-clinical trials. The results of this non-clinical trial are scheduled to be announced after the summer of 2023 and are expected to determine whether clinical development can be restarted, and Solasia Pharma is closely monitoring the results.

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	<p>*The world's only transdermal patch type 5-HT3 receptor antagonist</p> <p>*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.</p> <p>*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.</p>

(※)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.

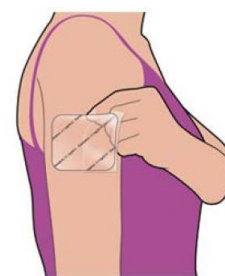
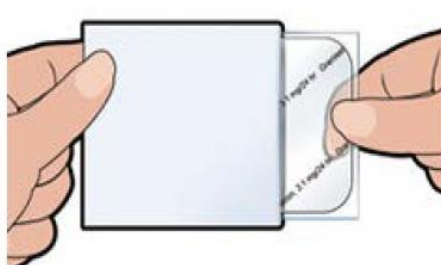
The damaged Chromaffin cells produce serotonin, a neurotransmitter, which is taken in by the 5-HT3 receptors in the peripheral vagus nerve. This stimulus is transmitted through the peripheral vagus nerve to the medulla oblongata via the chemoreceptor trigger zone

(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 thinking of negotiation for licensing out products under the assumption that the second/third phase clinical test (the final test) will be conducted at the licensee.

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.

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 : epiril® 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	<p>*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.</p> <p>* “episil® (SP-03)” contains no pharmaceutical agent, so there is no side effect nor interaction with anticancer agents.</p>
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(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	<ul style="list-style-type: none"> * There is currently no approved drug to prevent or treat CIPN * Superoxide dismutase mimetics to decompose 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.

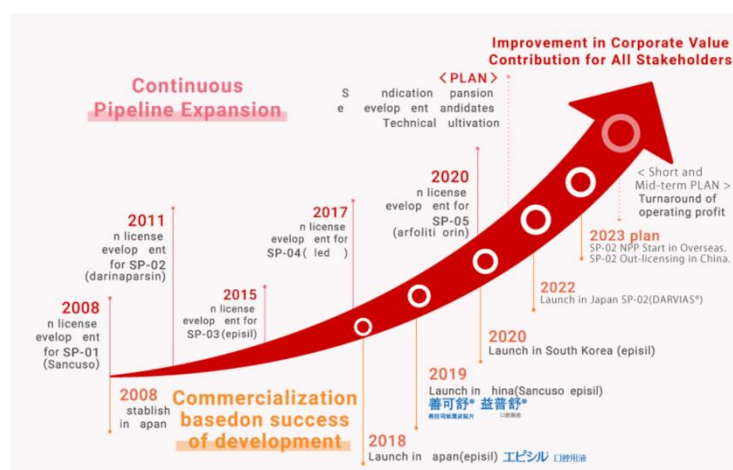
Although they are in the initial stages of research and development, the company is proceeding with initiatives that differ from the conventional "introduction, development, commercialization, or out-licensing" approach.

Project	Development Strategy and Background	Features
<p>The nucleic acid medicine RECQL1-siRNA project with GeneCare Research Institute Co., Ltd.</p>	<p>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.</p> <p>The company has already signed an option contract for licensing out products in this project with GeneCare Research Institute Co., Ltd.</p>	<p>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.</p>
<p>New RNA editing technology (Pentatricopeptide Repeat: PPR) project with Editforce Inc.</p>	<p>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.</p> <p>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.</p>	<p>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.</p>
<p>New Antibody Modification Technology (Quench Antibody: Q-body) Project with HikariQ Co.</p>	<p>Application of next-generation antibody-drug conjugates (ADCs) to drug development.</p>	<p>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</p>

	<p>Currently, preliminary evaluation is being conducted on ADC candidates using "Darinaparsin® (SP-02)" as a drug payload.</p>	<p>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.</p>
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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 Ending December 2023 Earnings Results

2-1 Overview of consolidated results

	2Q of FY 12/ 22	2Q of FY 12/ 23	YoY
Revenue	189	529	+340
Gross Profit	127	289	+162
R&D Expenses	347	192	-155
SG&A Expenses	1,008	559	-449
Operating Profit	-1,228	-462	+766
Profit before Tax	-1,233	-450	+783
Quarterly Profit	-1,247	-437	+810

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

The sales revenue in the second quarter of FY December 2023 was 529 million yen, up 340 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).

For Sancuso® (SP-01), the prescription volume was on a recovery trend due to the decline in the impact of the novel coronavirus infection, and shipment quantity increased as sales partners demanded stock increase in preparation for changing manufacturing sites to reduce manufacturing costs.

Research and development expenses decreased 155 million yen to 192 million yen.

Primarily, the expenses include investments for changing manufacturing facilities to reduce product costs and investments for studying the possibility of expanding the applications of Darvias® (SP-02) and for newly developed product candidates.

SG&A expenses decreased 449 million yen to 559 million yen. Fixed costs were reduced due to the dissolution of the self-selling system in China in the third quarter of the previous fiscal year.

As a result, operating loss decreased 766 million yen to 462 million yen.

2-2 Financial standing and cash flows

◎Main Balance Sheet

	End of December 2022	End of June 2023	Increase /Decrease		End of December 2022	End of June 2023	Increase /Decrease
Current assets	1,435	1,171	-264	Current liabilities	407	351	-56
Cash, etc.	803	453	-350	Trade payables	332	273	-59
Trade Receivables etc.	572	549	-23	Noncurrent Liabilities	64	93	+29
Inventories etc.	14	117	+103	Total Liabilities	472	445	-27

Noncurrent Assets	1,698	1,507	-191	Total Equity	2,662	2,233	-429
Intangible Assets	1,570	1,343	-227	Retained Earnings	-223	-661	-438
Total Assets	3,134	2,678	-456	Total Liabilities and Equity	3,134	2,678	-456

*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.

Total assets decreased 456 million yen from the end of the previous term to 2,678 million yen due to impairment losses on intangible assets and cash etc.

Total liabilities decreased 27 million yen from the end of the previous term to 445 million yen.

Due to the negative growth of retained earnings etc., total equity decreased 429 million yen from the end of the previous term to 2,233 million yen. Capital-to-asset ratio decreased 1.6% from the end of the previous term to 83.3%.

3. Fiscal Year Ending December 2023 Earnings Forecasts and Future Goals

3-1 Full-year earnings forecast

	FY 12/ 22	FY 12/ 23 Est.
Revenue	1,092	1,000 ~ 1,800
Operating Profit	-2,470	-1,150 ~ -350
Pretax profit	-2,492	-1,150 ~ -350
Net Profit	-2,548	-1,150 ~ -350

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

There are no changes to the earnings forecast. Forecasted increase in revenue and narrowing of losses.

◎Revenue

The sales revenue for FY December 2023 is expected to be at least 1 billion yen, by summing up the sales revenues of "Sancuso® (SP-01)," "Episil® (SP-03)," and "DARVIAS® (SP-02)," which was released in Aug. 2022. However, these products are still in the stage of sales expansion, and their market penetration is estimated to be limited compared to the expected business scale.

Considering the possibility of concluding a contract for licensing out "DARVIAS® (SP-02)" in China, it is expected that the sales revenue will be up to 1.8 billion yen, including the additional sales of 0.8 billion yen from the lump-sum payment for the contract. Due to COVID-19, there are significant uncertainties over the sale of products, the possibility of licensing, and the contract amount for licensing.

◎Operating expenses

For "Sancuso® (SP-01)," "Episil® (SP-03)," and "DARVIAS® (SP-02)," it is assumed that they includes the cost for sales, the investment in limited marketing activities, including post-release surveys, and 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 450 million yen.

As a result, the company is expecting to post an operating loss and other losses ranging from 350 million yen to 1,150 million yen.

3-2 Main Business Goals

「DARVIAS® (SP-02)」

To secure sales revenue and revenue from the launch of the NPP system and licensing-out in China.
To increase indications in collaboration with Nippon Kayaku Co., Ltd.

「Sancuso® (SP-01)」 「Episil® (SP-03)」

To continue the manufacturing site to reduce manufacturing costs.

「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.

To conduct investments in R&D of other candidates and technologies, including nucleic acid drugs, gene therapy, and Darinaparsin ADC.

3-3 Short- and Mid-term basic management policy

To enhance the value of existing assets: 3 products "Sancuso® (SP-01)," "Episil® (SP-03)," "DARVIAS® (SP-02)," the developed product "PledOx® (SP-04)," and candidates/technologies," and achieve single-year profitability early, excluding research and development expenses.

The company will also continue to consider introducing new developed products in the later clinical stage, taking into account profit/loss, financial situations, and opportunities, including the collaboration with other companies.

The company believes that it can achieve sufficient corporate value improvement through investment in and development of its existing three assets, PledOx® (SP-04), and candidates/technologies.

* 「Sancuso® (SP-01)」

Sales performance is still below expectations, but the company believes that it is reliably meeting demand and will strive to reduce manufacturing costs by relocating the manufacturing site to improve profitability.

The company also considers that it is possible to increase indications for "Sancuso® (SP-01)."

* 「DARVIAS® (SP-02)」

In addition to increasing indications beyond peripheral T-cell lymphoma, the company aims to achieve a synergistic effect through combination with other drugs for peripheral T-cell lymphoma.

* 「Episil® (SP-03)」

Like in the case of "Sancuso® (SP-01)," the company will strive to reduce manufacturing costs by relocating the manufacturing site while accumulating sales.

* 「PledOx® (SP-04)」

To continue non-clinical trials for taxane formulations.

4. Conclusions

The future of the business of licensing out Darvias® (SP-02) in China remains a major focus. In negotiations with licensees, the deciding factors include economic conditions, future sales volume forecasts and the outlook for the approval process in China. Negotiations are underway with multiple companies. Each company presents its own terms and conditions. Solasia Pharma wants to make a comprehensive decision while focusing on economic conditions.

The company decided to suspend the development of arfolitoxorin SP-05, but in July 2023, ISOFOL, which is the joint developer and licensing company, announced that it is expected to have antitumor effects if the dosage and administration method are changed. It

announced the results of the reanalysis of the data from the phase III clinical trial (AGENT trial) and the implementation of non-clinical trials. The results of these non-clinical trials are scheduled to be published after the summer of 2023 and are expected to determine whether clinical development can be restarted. Solasia Pharma is closely monitoring and anticipating the results.

At the end of last year, the situation was very difficult with the end of China's self-sales system and the suspension of the development of SP-05. The company has reached bottom and the company has completed a significant reorganization, so the atmosphere within the company is very positive, and that was clear during the interview. The non-clinical trial results for SP-05 are expected to be released before the announcement of financial results for the third quarter, and we look.

<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.”

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