Pharmaceutical company specialized in oncology and rare disease

# Solasia Pharma K.K. (4597•TSE Mothers)

Recommendation rating (July 11)

**Overweight**

| Stock Price | Unit of Investment | Market Cap | 52-Week High | 52-Week Low | PER(E) |
|---|---|---|---|---|---|
| 398yen (7/11) | 100Shares | 348.7Bil yen (7/11) | 652yen (17/5/17) | 219yen (17/3/29) | - (7/11) |

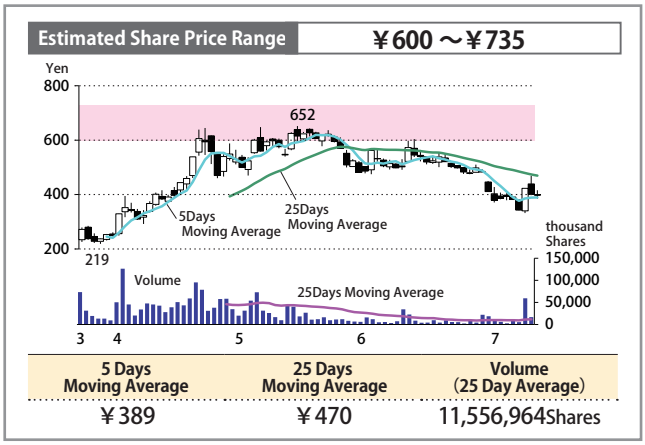
## Faster growth by building up own distribution capability in China and high-potential drug 'SP-02'

### ■Speeding up investment in China business, while expanding R&D expenses

In its consolidated financial results (under IFRS) for 1Q (January ~ March 2017) of the fiscal year ending December 31, 2017 (FY2017), Solasia Pharma K.K. reported sales revenue of 3 million yen (down 98.2 % compared with the same period last year) and an operating loss of 243 million yen (it recorded a loss of 55 million yen for the same period a year ago). The company blamed the operating loss on the fact that it posted no milestone revenue (a non-recurring revenue) in the quarter however it recorded a milestone revenue in the same period last year; also, it suffered up-front development costs together with expenses for stock exchange listing preparations.

**Solasia Pharma's development pipelines have made solid progress. At their core are two supportive care products (which control adverse effects induced by cancer chemotherapy and radiation).** In 2014, Solasia submitted a New Drug Application for 'SP-01' to the authorities in China, where it holds commercialization rights. The medicine is an adhesive skin patch that prevents chemotherapy-induced nausea and vomiting, which is now very close to being approved. Solasia holds commercialization rights to 'SP-03' in Japan and China. 'SP-03' is a medical device (administered as a bioadhesive liquid) effective for the alleviation of pain associated with oral mucositis, caused by chemotherapy and radiotherapy. In July 6, 2017, the company obtained approval from the Japanese Ministry of Health, Labour and Welfare to commercialize 'SP-03'. It expects to obtain approval for 'SP-03', from the Chinese authorities by the end of 2017 or the beginning of 2018.

For the full consolidated FY2017, Solasia Pharma projects sales revenue to come to 423 million yen (down 15.6 % from the previous year) and an operating loss of 1,787 million yen (compared with the previous year's loss of 462 million yen). The forecast in operating loss largely reflects the expected increase in the recruitment of MRs (medical representatives) in Chinese major cities (Beijing, Shanghai and Guangzhou) and marketing spending, alongside higher R&D expenses for pivotal clinical testing of 'SP-02', a therapeutic agent for the treatment of peripheral T-cell lymphoma. The recruitment of MRs are to prepare and solidify its own Chinese operational bases for FY 2018. 'SP-02', which is under clinical study, has the potential to adapt not only to hematologic cancers such as malignant lymphoma and leukemia but also to solid tumors. The final clinical study phase for SP-02 is expected to complete in 2018, therefore the company may receive a milestone revenue concerning the medicine within FY2019.




### ■Heading toward profitability in FY2019

Solasia Pharma does not operate nonclinical studies, including basic research and pharmaceutical studies or animal testing designed to discover new drugs. It focuses its resources on pharmaceutical development (i.e. the process spanning clinical studies to seeking and obtaining approval from relevant countries' pharmaceutical regulating authorities) to sales and marketing functions. Mr. Yoshihiro Arai, Solasia Pharma's president and CEO, has developed his stellar career in roles such as head of clinical development at the Japanese arm of Amgen, a large U.S. Biotechnology-based drug company. The company boasts talented group of specialists in the clinical development field. Solasia's business model is to in-license assets which have already been approved in U.S.A., Europe and other countries, indicating that its risk of failure in clinical development is low. In addition, the company has built strong relationships with key opinion leaders which is an advantage for conducting smooth clinical trials (drug tests concurrently with patient treatment) and leads to efficient new drug development.

**It is expected that Solasia Pharma will continue to post a net loss through FY2018, saddled with up-front investment costs. However, Morningstar believes that the company is highly likely to move into the black in FY2019, during which it is expected to see revenue growth thanks to the contribution from its own distribution channel in Chinese major cities, the royality revenue for 'SP-01' and 'SP-03' in China and receipt of a milestone revenue related to the 'SP-02' development.**

### Revenue and Earnings Trend (As of July 11)

| | | Revenue (Yen Mil) | YoY (%) | Operating Profit (Yen Mil) | YoY (%) | Pre-tax profit (Yen Mil) | YoY (%) | Net Profit (Yen Mil) | YoY (%) | EPS (Yen) |
|---|---|---|---|---|---|---|---|---|---|---|
| 2015-12 | Past Results | 229 | - | -702 | - | -701 | - | -643 | - | -24.8 |
| 2016-12 | Past Results | 501 | 2.2 times | -462 | Deficit reduction | -494 | Deficit reduction | -474 | Deficit reduction | -18.5 |
| 2017-12 | Company est. | 423 | ▲15.6 | -1,787 | Deficit expansion | -1,793 | Deficit expansion | -1,798 | Deficit expansion | -22.6 |
| | MS est. | 423 | ▲15.6 | -1,787 | Deficit expansion | -1,793 | Deficit expansion | -1,798 | Deficit expansion | -22.6 |
| 2018-12 | MS est. | 1,050 | 2.5 times | -1,300 | Deficit reduction | -1,300 | Deficit reduction | -1,305 | Deficit reduction | -14.9 |

Following the turnaround, we anticipate its profitability will improve significantly, driven by accelerated growth in sales of the 3 assets. Based on our five-year earning forecast and using the DCF (discount cash flow) method, we estimated Solasia Pharma's share price to be in the range of 600－735 yen. Near-termly, the company share prices softened at one point as JapanBridge (Ireland) Limited, one of the major shareholders, transferred and sold out all of its stake. Following that, share prices have shown a sign of recovery as the market favored the approval of 'SP-03' by the Japanese authorities. In consideration of the company's growth potential, the share price appears not to reflect fully the company's true value. We commence our valuation of Solasia Pharma shares with an 'Overweight' rating. (Takahiro Arimura)

## ■Company Overview

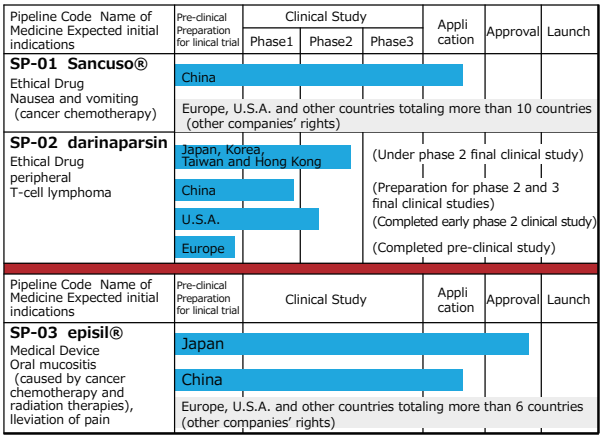
Solasia Pharma K.K. was established in 2006, formed as a joint venture between Itochu Corporation and MPM Capital, Inc., a U.S. bio-venture capital firm. The company operates by trying to identify 'drug lag' opportunities in which medicines that have been approved and marketed in the U.S.A., have not been approved in the Asian market, including Japan and China. Its business model is to in-license assets concerning oncology drugs or related products from U.S. and European pharmaceutical ventures and other firms, conduct clinical trial, obtain approval and launch in the market, and promoting those drugs through its own-distribution channel (or out-license to pharmaceutical companies) in Asia. In the pharmaceutical industry, Solasia Pharma is positioned close to large and medium-sized pharmaceutical companies; but it focuses on oncology and rare disease, in which the large drug companies, that pursue a larger earnings performance, pay little attention. This demonstrates the uniqueness of Solasia Pharma's position. There are 3 assets in its development pipeline. The company features a group of clinical development specialists. They boast 'superior ability to identify' which developed drugs are likely to be given early approval from relevant countries' authorities. These specialists have helped the company achieve highly efficient new drug development.

## ■ Business Environment and Outlook

Cancer incidence and cancer mortality rates have continued to rise consistently. According to the company data, cancer mortality in Japan was roughly 70 per 100,000 a year in the early postwar period but in 2015 the rate rose to almost 300 per 100,000. The cancer incidence in China for 2011 approached 150,000. Considering this, it is said that the oncology and related drugs market has no limit. New drugs are not allowed to be launched or distributed in the market before they are approved by the relevant country's authorities. These new drugs are not approved unless they can demonstrate higher overall benefits than existing ones. Most cancer chemotherapies apply multiple anticancer agents, and different agents are often administered to recurrent cancers. These practices have encouraged a steady increase in the number of oncology drugs.

Meanwhile, in the Chinese market, where Solasia Pharma is set to concentrate on enhancing its own-distribution channel, there is an estimated 70 billion yen in demand for supportive care medicine that prevent chemotherapy-induced nausea and vomiting. New drug applications for anticancer medication need to be filed with respect to the individual organs affected by cancer. However, supportive care medicine can be applied to any cancer therapy-induced effects, demonstrating great potential to adapt. In the long and medium term, the company aims to acquire 30－40 % share of the 70 billion yen market.

**Solasia Pharma's Product Pipelines**

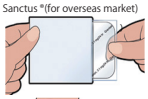


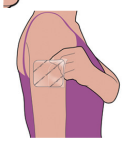

※Blue bar graphs in the above diagram represent the company's product pipelines.

Source: The company's information

**Features of 'SP-01' Granisetron Transdermal Delivery System**

Sanctus ®(for overseas market)





- **It is the only transdermal delivery system (adhesive skin patch) in the world,** using 5-HT3 receptor antagonists in the world.
- It can be applied to outpatients diagnosed with cancer too.
- It can be applied to patients who are not able to swallow medicines due to nausea/vomiting and mucositis.
- **U.S. NCCN* and Chinese clinical guidelines recommend prescribing this system.**
- **Countries in which it is already approved and marketed: USA, UK, Germany, Netherlands, Denmark, Spain, Finland, Norway, Sweden, Kuwait, Lebanon, Qatar, Bahrain, UAE, Libya, Saudi Arabia, Korea, Taiwan, Hong Kong, Philippines and Australia**

※ NCCN is a non-profit organization comprising 25 major cancer centers in the world.

Source: The company's information

## Risk Factors

Businesses in the pharmaceutical industry need to comply with various countries' laws and enforceable agencies that oversee their operations, comprising research, development, manufacturing and marketing. These include each country's law relating to pharmaceuticals and medical devices, pharmaceutical administration, medical insurance plans and other relevant regulations. This means that substantial modification to any of these regulations or controls, including pharmaceuticals and medical devices law, may have critical influence on Solasia Pharma's financial standing and earnings. Separately, the company operates its business in Asia with a focus on Japan and China. Especially, its China business makes a significant contribution to its earnings. In China, the company plans to implement a business model in which it deploys MRs and collaborates with a number of pharmaceutical wholesalers using its own-distribution channels in major cities. However, the company may come under pressure if the own-distribution channel project stagnates.

# Shareholder Return (As of July 11)

## ■ Dividends

| | | Dividend Per Share | | |
|---|---|---|---|---|
| | | Midterm | Year-End | Annual |
| 2015-12 | Past Results | ¥0 | ¥0 | ¥0 |
| 2016-12 | Past Results | ¥0 | ¥0 | ¥0 |
| 2017-12 | Company est. | ¥0 | ¥0 | ¥0 |

## ■ Shareholder Special Benefits

None

## Competitor Comparison (If the number is better than rivals, it's highlighted by red character) (As of July 11)

| | | Solasia Pharma K.K. (4597・TSE Mothers) | Sosei Group Corporation (4565・TSE Mothers) | SymBio Pharmaceuticals Limited (4582・JASDAQ) |
|---|---|---|---|---|
| Basic Point | Stock Price | ￥398 | ￥12,110 | ￥262 |
| | Unit of Investment | 100Shares | 100Shares | 100Shares |
| | Minimum Investment Amount | ￥39,800 | ￥1,211,000 | ￥26,200 |
| | Fiscal Year End | December | March | December |
| Share Price Indicator | PER (E) | - | - | - |
| | PBR | 7.5 | 7.1 | **2.4** |
| | Dividend Yield (E) | 0.0% | 0.0% | 0.0% |
| Growth | Revenue Growth Rate (E) | ▲15.6% | - | **22.6%** |
| | Operating Profit Growth Rate (E) | - | - | - |
| | EPS Growth Rate (E) | - | - | - |
| Profitability | Operating Margin (E) | - | - | - |
| | ROE | ▲21.4% | **37.7%** | ▲50.4% |
| | ROA | ▲12.6% | **26.2%** | ▲39.1% |
| Financial Health | Equity ratio | **92.7%** | 60.0% | 73.5% |
| | Debt-Equity Ratio | **0.0%** | 30.6% | 8.9% |
| | Current Ratio | **494.7%** | 307.5% | 709.7% |

We chose: Sosei Group Corporation (4565) as it implements a similar business model to Solasia's from the in-licensing of newly developed drugs to clinical studies, and SymBio Pharmaceuticals Limited (4582) which focuses on hematologic cancers.

### ■Growth

In FY2017, Solasia Pharma forecasts receipts of milestone revenue following the approval of two developed supportive care products; but the actual amount of milestone revenue and other revenue for FY2017 is expected to fall short of that posted the previous year. Meanwhile, its operating loss is likely to worsen as the company anticipates higher costs arising from the expanded strategic investment in China business and added R&D spending on the development of oncology drugs. In the near-term period, up-front investments will precede earnings; therefore we forecast that first revenue growth and operating profit will be seen in FY2019.

Regarding industry peers' comparisons, SymBio Pharmaceuticals, that forecasts growth in hematologic cancer-related anticancer drug sales, outshines Solasia Pharma in terms of revenue growth but SymBio expects to post a larger operating loss year-on-year in the wake of expanded R&D spending.

### ■Profitability

As Solasia Pharma continued to suffer profit losses thanks to up-front investments, both its ROE (return of net income on equity) and ROA (return of ordinary income on total assets) were negative. However, the breakdown of ROE showed that its financial leverage of 176.5 % was at a relative mid position. The company enhanced its equity capital after it issued new shares, mainly to fund research and development operations, resulting in a continual improvement in its financial leverage.

On the other hand, another competitor, Sosei Group Corporation has seen a phase of revenue expansion despite its R&D spending burden. For the fiscal year to December 31, 2016, Sosei posted a milestone revenue from Allergen plc, a large U.S. based pharmaceutical firm, which significantly contributed to its consolidated financial results and drove both ROE and ROA into positive territory.

### ■ Financial Health

Solasia Pharma sustained a high level of equity to total assets of 92.7 % at the end of FY2016. With no interest-bearing debts, its debt to equity ratio stayed at a low level. Its liquidity ratio was 494.7 % with a large proportion of current assets, demonstrating a sound balance sheet. The company procured funds of approximately 3.8 billion yen through an initial public share offering, when it was listed on the TSE's Mothers market.

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# How to Read Morningstar Equity Research Report

## Our Uniqueness

### (1) Emphasize Its Position as an Independent Evaluation Organization

Morningstar emphasizes its position as an independent evaluation organization and is committed to providing objective comparison and assessment in the Morningstar Equity Research Report. For all stocks covered by us, we determine investment decisions, estimated share price range and earnings forecasts based on expertise of an individual analyst as well as the stock assessment committee consisting of several analysts.

### (2) Universe of Covered Stocks

The stock assessment committee selects covered stocks based on the following criteria.

**【Stock Selection Criteria】**

- Domestic emerging companies that are rarely covered by analysts
- Stocks that are popular among retail investors (refer to data from online security brokers)
- Size of market capitalization (over about 5 billion yen)
- Exclude stocks which are liquidated or trade control, or stocks with going concern and excessive debt

### (3) Investment Decisions Classified into Three Groups

We determine investment decisions for covered stocks after consultation with the stock assessment committee based on research, interview and analysis by each Morningstar analyst.

Each stock is classified into either of three groups according to the following criteria.

Overweight : Forecasted to go beyond the current stock price level by 15% or more in the next 6 months.

Neutral : Forecasted to fall into the range of -15% ~+15% of the current stock price level in the next 6 months.

Underweight : Forecasted to go below the current stock price level by 15% or more in the next 6 months.

We flexibly respond to any changes of observations regarding earnings forecasts, financial situations and stock price trends, and change investment decisions accordingly. "Under Review" status may be applied if any new information comes out and extra time is needed to determine investment decisions. Also we don't change investment decisions during trading hours. "Suspension" status may be applied when an analyst leaves our company.

### (4) Estimated Share Price Range in the Medium Term

It shows the price range for a stock price in the next 6 months. We determine upper and lower range of stock price based on fair value estimates from share price indicator, technical factors such as chart points, most recent high and low prices, trend line and moving average, trading volume in each price range and such.

## Analysis Points

### ■ Analyst Comment

Each analyst reports and evaluates the most recent earnings trend and business environment. It shows the most important information for stock investment such as evidence for investment decisions, perspectives on earnings forecasts and business prospects. Also to make sure it is easy to comprehend, we write in 2-4 paragraphs and use bold to emphasize important texts.

### ■ Revenue and Earnings Trend

It reports earnings in past two fiscal years, company forecasts and our forecasts for the current and next fiscal year. We predict earnings based on research as well as past quarterly earnings trend and analysis by segments.

### ■ Company Overview

It explains in detail what businesses the company is engaged in and how revenue sources are defined. Also on the basis of our research, it discusses what businesses the company will focus on in years to come and how it carries out mid-term business plan.

### ■ Business Environment and Outlook

It discusses current circumstances and growth potential of the industry to which the company belongs. A comprehensive report on the industry from different perspectives is provided through research interviews to competitors. Specific figures of the industry data are also introduced.

### ■ Risk factors

It shows the company's risk factors and describes various aspects of risks such as business, earnings and financials. Typical stock market risks are also taken into consideration.