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To: All Concerned Parties

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Business Overview of Pipeline Products
(Third Quarter of the Fiscal Year Ending December 31, 2026)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending December 31, 2026. The Company hereby provides an update on the status of its major pipeline products as supplementary information to the financial results.

Commercial Products Under Development

Product	Development code	Indication	SolasiaTerritory	Pre-clinical	Clinical development Stage P1	P2	P3	NDA	Approval・Launch
Sancuso®	SP-01	Chemotherapy induced nausea and vomiting (CINV)	China						China
Darvias®	SP-02	Peripheral T-cell lymphoma (PTCL) Additional indication under review	Worldwide						Japan ※Non-clinical studies for indication expansion are currently ongoing. South America ※Marketing authorization applications have been submitted in Colombia and Peru. ※Marketing authorization applications are being prepared for filing in Ecuador and Panama.
episil®	SP-03	Pain associated oral mucositis (medical device)	Worldwide						Japan, China, Korea Brazil
PledOx®	SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, China						Japan ※In 2020, the Phase III international clinical trial for platinum-induced CIPN did not meet its primary endpoint. ※Non-clinical studies for taxane-induced CIPN are currently ongoing
Arfolitixorin	SP-05	Colorectal Cancer	Japan						Germany ※2025: Isofol initiated the Phase Ib clinical trial with an optimized dosing and administration regimen. ※2026: Administration at the final dose level (500 mg/m²) was initiated in the dose-escalation Phase Ib part of the Phase Ib/II clinical trial. ※In Japan, a Phase II clinical trial is scheduled to commence between the fourth quarter of FY2026 and early FY2027.

■ Development Candidates / Technology Projects

- Nucleic Acid Medicine Project for Peritoneal Dissemination (GeneCare Research Institute Co., Ltd.)
- Gene Therapy Project Utilizing RNA Editing Technology (EditForce Inc.)
- Drug Discovery Project Using Novel Antibody Modification Technology (HikariQ Health Co., Ltd.)
- Joint Commercialization Project for Functional Fluorescent Probe Technology (Goryo Chemical Inc.)

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Marketed Products

■ Sancuso® (Development Code: SP-01, Chinese Product Name: 善可舒®)
-Granisetron transdermal delivery system-

- Indication: Chemotherapy-induced nausea and vomiting
- Territory under the Company's Rights: China
- Out-licensing Partner: MAAB Pharma Limited

Status in China

- In January 2026, the Company entered into a license agreement with MAAB Pharma Limited (MAAB), its new sales partner in China, and MAAB commenced sales activities in April 2026. During the nine months ended September 30, 2026, the transition of sales operations from Lee's Pharmaceutical to MAAB and the Company's shipment of products to MAAB were completed, and the Company recognized product sales revenue. The Company has also granted MAAB manufacturing rights in China and continues initiatives toward potential local production.
- As announced on October 19, 2026, the Company received a portion of the installment payments under the license agreement with MAAB and recognized the corresponding revenue in the third quarter of 2026.

Other updates

- The Company and MAAB continue to evaluate and consider strategic collaboration regarding the Company's products and pipeline products other than Sancuso®.

■ DARVIAS® (Development Code: SP-02, darinaparsin): Organic arsenic compound

- Indication: Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL)
- Territory under the Company's Rights: worldwide

Status in Japan

- Out-licensing Partner: Nippon Kayaku Co., Ltd.
- In June 2022, manufacturing and marketing approval was obtained, and product sales were initiated in August 2022.

Status in South America

- Out-licensing Partner: HB Human BioSciences SAS
- The new drug application (NDA) for DARVIAS® was accepted by the health authorities in Colombia in December 2023 and in Peru in March 2025, and preparations for filing an application in Ecuador and Panama are currently underway.

Other updates

- The Company continues to evaluate potential indications beyond relapsed or refractory PTCL, including Epstein–Barr virus-positive malignancies and malignancies with high expression of the xCT transporter. Non-clinical studies using cell lines of potential cancer types are underway at a university laboratory in Japan and a research institution in China.
- In October 2026, the final analysis results of an observational study of DARVIAS® in patients with relapsed or refractory peripheral T-cell lymphoma were presented at the 88th Annual Meeting of the Japanese Society of Hematology.

■ episil® oral liquid (Development Code: SP-03): Hydrogel Wound Coating and Protective Material

- Intended Use: Management and relief of oral pain associated with cancer therapy
- Territory under the Company's Rights: Worldwide

Status in Japan

- Out-licensing Partner: Meiji Seika Pharma Co., Ltd.
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Status in China

- Out-licensing Partner: Changchun GeneScience Pharmaceutical Co., Ltd.
- GeneScience continues product sales in China under a new sales structure following its organizational changes. Shipments to China have remained at a low level during fiscal 2026.

Status in Korea

- Out-licensing Partner: Synex Co., Ltd.

Status in Brazil

- Out-licensing Partner: Daiichi Sankyo Brasil (planned local product name: "Epifilm")
- In August 2025, the Company entered into an exclusive distribution license agreement for Brazil with Daiichi Sankyo Brasil, a Brazilian subsidiary of Daiichi Sankyo Company, Limited. In July 2026, the notification number issued by the Brazilian Health Regulatory Agency (ANVISA) was officially published, enabling commercialization in Brazil. Daiichi Sankyo Brasil plans to commence sales under the product name "Epifilm" during the fourth quarter of 2026, and the Company has begun supplying the product to Daiichi Sankyo Brasil.

Other updates

- episil® was included in the Clinical Practice Guidelines for the Treatment of Oral Cancer in Elderly Patients, compiled by the Japanese Society for Oral Oncology.
- The Company obtained certification under ISO 13485, the international standard for medical device quality management systems.

1. Pipelines Under Development

■ SP-04 (PledOx®): Intracellular superoxide dismutase mimetic

- Planned indication: Chemotherapy-induced peripheral neuropathy (CIPN)
- Territory under the Company's Rights: Japan, China, South Korea, Taiwan, Hong Kong, and Macau
- Out-licensing Partner in Japan: Maruho Co., Ltd.
- In 2020, in light of the results of the international Phase III clinical studies (POLAR-A and POLAR-M), which included Japan and targeted chemotherapy-induced peripheral neuropathy caused by oxaliplatin-containing multidrug regimens in colorectal cancer patients and did not meet the primary endpoints, the licensor (Egetis Therapeutics) and the Company suspended development for this indication.
- The Company is currently conducting new non-clinical studies at a university laboratory in Japan to investigate the mechanism of action of SP-04, with the aim of exploring its development potential for taxane-induced peripheral neuropathy.

Other updates

- In March 2026, a laboratory at a domestic university presented the results of a collaborative study using animal models on the efficacy of SP-04 against taxane-induced peripheral neuropathy (146th Annual Meeting of the Pharmaceutical Society of Japan).

■ SP-05 (arfolitixorin): Folate Formulation Designed to Enhance Antitumor Efficacy

- Planned Indication: Enhancement of the Antitumor Effect of 5-Fluorouracil (5-FU) in colorectal cancer
- Territory under the Company's Rights: Japan
- In 2022, the international Phase III clinical study (AGENT study) did not meet its primary endpoint or key secondary endpoints, and development was suspended. Subsequently, based on post-hoc analyses and additional non-clinical study results, the licensor, Isofol

Medical AB (Isofol), decided to resume development in 2024, and the Company also decided to resume development in Japan.

- Post-hoc analyses of the AGENT study reported higher efficacy in the SP-05 group than in the leucovorin control group among patients who strictly adhered to the study protocol. Based on these findings, Isofol initiated a Phase Ib/II clinical study in Germany in April 2025 using optimized doses and administration timing.
- In July 2026, evaluation of the third dose level (300 mg/m²) in the dose-escalation Phase Ib part was completed without dose-limiting toxicities. Following the recommendation of the Safety Review Committee, the study progressed to evaluation at the final dose level (500 mg/m²). To accelerate patient enrollment, Essen University Hospital was added as a study site in August 2026. Isofol continues to plan the initiation of the Phase II part.
- In Japan, based on the results of the ongoing Phase Ib part in Germany, the Company plans to initiate a separate Phase II clinical study with the same design as the German Phase II part between the fourth quarter of fiscal 2026 and early fiscal 2027.

Other updates

- The Company holds approximately a 3.25% equity stake in Isofol with the aim of strengthening collaboration with Isofol and partially capturing economic value generated from development progress outside Japan.

2. Development Candidates / Technology Projects

- The following development candidates and technologies are early-stage projects in the research or pre-clinical development stages. Depending on research and development progress, they may be designated as the Company's pipeline products. Under joint research and development agreements with partner companies, the partners primarily plan and conduct non-clinical studies and related activities.

■ Nucleic acid drug candidate for peritoneal metastases

- In 2020, the Company entered into an agreement with GeneCare Research Institute Co., Ltd. ("GC") concerning an exclusive negotiation right (option) to acquire rights to GC's nucleic acid drug candidate RECQL1-siRNA and related technologies. The Company is currently conducting joint research and development with GC and plans to consider exercising the option based on progress in non-clinical studies and new formulation development.
- RECQL1-siRNA is a small interfering RNA (siRNA; short double-stranded RNA) created by GC based on technology licensed from Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY) in the United States and is a nucleic acid drug candidate. It is expected to induce cancer cell death through a novel mechanism of action that selectively suppresses the expression of RECQL1, a DNA repair helicase overexpressed in cancer cells. Multiple pharmacological studies have shown inhibition of tumor growth in various cancer types and prolonged survival in animal models of peritoneal dissemination associated with advanced ovarian and gastric cancers.
- The Company and GC are conducting animal studies at a university laboratory in Japan to evaluate efficacy against ovarian cancer cell lines, using a prototype lipid nanoparticle (LNP) formulation containing novel siRNA sequences developed through joint research with the Ui-Tei Laboratory at the Graduate School of Science, the University of Tokyo.

Note: Peritoneal dissemination is a type of metastasis observed in ovarian or gastric cancer patients, in which cancer cells migrate to the peritoneal cavity and spread like seeds scattered in the soil. As the condition progresses, it may be accompanied by malignant ascites, and the prognosis is poor. Systemic chemotherapy has not been sufficiently effective in treating peritoneal dissemination, and novel local treatments, such as intraperitoneal administration of drugs, are under investigation.

■ Drug discovery utilizing RNA editing technology (gene therapy)

- In 2019, the Company entered into a joint research and development agreement with EditForce, Inc., a biotechnology venture originating from Kyushu University. The Company is evaluating applications of EditForce's RNA editing technology to the discovery of gene therapies in oncology and other fields.

- The Company is currently evaluating the applicability of PPR technology to Niemann–Pick disease, a hereditary and progressive lysosomal disorder.

■ **Drug discovery using novel antibody modification technology**

- In 2022, the Company entered into a capital and business alliance agreement with HikariQ Health Co., Ltd., a biotechnology venture startup originating from Tokyo Institute of Technology (currently Tokyo Science University), primarily through an equity investment.
- HikariQ's Q-body platform technology works by incorporating fluorescent dyes within the antibody constituting a Q-body, where their fluorescence is quenched. When the antibody reacts with an antigen, the dyes are displaced and emit fluorescence. Q-bodies therefore function as biosensors whose fluorescence intensity varies with antigen concentration.
- Immunoassay technology based on this mechanism is expected to substantially simplify testing and reduce costs compared with conventional immunological assays. HikariQ is also pursuing joint research and development with other companies in its immunoassay business.

■ **Joint commercialization of functional fluorescent probe technology**

- In 2023, the Company entered into an agreement with Goryo Chemical, Inc. to evaluate joint commercialization. The parties are assessing the feasibility of joint business development and clinical development of navigation drugs for cancer surgery and other applications using Goryo's functional fluorescent probe technology.
- Goryo continues to evaluate development and commercialization in Japan and the United States for GCP-006, a navigation drug targeting breast cancer.
- In July 2025, Goryo's new project, "Development of a performance evaluation system for newly synthesized trypsin and domestic manufacturing development of human gene sequence-type GMP trypsin," was selected under the regular category of the FY2025 Go-Tech Program (Growth-oriented SME Research and Development Support Program) of Japan's Ministry of Economy, Trade and Industry. The Company serves as an advisor to the project.

3. Corporate information

■ Financial results for the Third Quarter of the Fiscal Year Ending December 31, 2026

- For the nine months ended September 30, 2026, revenue totaled JPY 346 million, comprising product sales and related revenue from Sancuso® (SP-01) and episil® (SP-03), installment license fee revenue from Sancuso®, and milestone revenue related to episil® in Brazil. Gross profit was JPY 187 million. Revenue consisted of JPY 237 million in product sales and related revenue and JPY 108 million in license agreement revenue.
- Research and development expenses totaled JPY 352 million, primarily for cost reduction and evaluation of additional indications for DARVIAS® (SP-02), animal studies for SP-04, preparations for clinical studies of SP-05, and investment in new development candidates.
- Selling, general and administrative expenses totaled JPY 511 million. After deducting research and development expenses and selling, general and administrative expenses from gross profit, operating loss was JPY 676 million and quarterly loss was JPY 680 million.
- For fiscal 2026, product sales and related revenue are forecast at JPY 350 million (previous forecast: JPY 420 million), with corresponding cost of product sales of JPY 190 million. The Company continues to refrain from disclosing forecasts for license agreement revenue and total revenue.

4. Major shareholders information

- As of September 30, 2026, according to the Company's shareholder register, the largest shareholder was Nippon Kayaku Co., Ltd. (ownership ratio: 4.38%), the domestic partner for DARVIAS®, followed by Maruho Co., Ltd. (ownership ratio: 4.14%), the domestic partner for SP-04.

The Company is a specialty pharma company, specializing in the development and commercialization of products in the oncology field. In the United States, which is home to numerous successful biopharma venture companies, most of those companies post losses on a single-year basis. We believe that this situation exists because the marketplace places greater importance on making proactive upfront investments in promising drug development than on assessing such companies based on their single-year gains and losses. At present, the Company is operating in accordance with this sort of business strategy. In addition to the operating results and other financial information in our earnings reports, we believe it is important to disclose to investors information about our key pipeline products to a certain level of detail. We have disclosed such business information in this report.

Disclaimer:

The forward-looking statements, including earnings forecasts, contained in this press release are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Such statements should not be construed as representing commitments on the part of the Company. Please be aware that actual performance may differ for a variety of reasons. Major factors affecting the Company's actual performance include the economic conditions in which it operates, exchange rate fluctuations, the competitive situation, and other factors. Information about pharmaceuticals and medical devices (including products under development) is not provided for the purposes of advertising or medical advice.