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To: All Concerned Parties

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

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for the Second quarter of the Fiscal Year Ending December 31, 2026. The Company hereby supplements this information by providing an update on the status of its major pipeline products.

Commercial Products Under Development

Product	Development code	Indication	SolasiaTerritory	Pre-clinical	Clinical development Stage			NDA	Approval・Launch
					P1	P2	P3		
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 in the process of submission 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				
Arfoltixorin	SP-05	Colorectal Cancer	Japan	Germany					
				※2025: Isofol initiated the Phase Ib clinical study using an optimized dose and dosing regimen. ※2026: Administration up to the third dose level (300 mg/m ²) in the dose-escalation Phase Ib part of the Phase Ib/II clinical study was completed. ※A separate Phase II clinical study is scheduled to commence in Japan between the second half of fiscal 2026 and the beginning of fiscal 2027.					

■ 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.)

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 April 2026, MAAB commenced sales activities following the transfer from Lee's Pharmaceutical and continued its initiatives toward local production in China.
- During the second quarter of 2026, the Company completed shipment of products to MAAB and received payment for product sales (USD 1,299,240). However, as certain documentation procedures associated with the change of the sales partner had remained incomplete as of the end of the second quarter, revenue from these product sales was scheduled to be recognized in the third quarter of the current fiscal year. As of the date of this announcement, the documentation procedures have been completed, and the related revenue has been recognized.

Other updates

- MAAB is evaluating and considering strategic collaboration with the Company regarding 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 is evaluating the expansion of indications beyond relapsed or refractory PTCL, including EB virus-positive malignancies and malignancies with high expression of the xCT transporter.
- In July 2026, Professor Toshihide Suzuki's research group at the Faculty of Pharmaceutical Sciences, Teikyo University, presented a poster on the mechanism of action of DARVIAS® (generic name: darinaparsin) at the 53rd Annual Meeting of the Japanese Society of Toxicology.

■ 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.

Status in China

- Out-licensing Partner: Changchun GeneScience Pharmaceutical Co., Ltd.
- GeneScience continues product sales under the new sales structure.

Status in Korea

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

Status in Brazil

- Out-licensing Partner: Daiichi Sankyo Brasil Farmacêutica Ltda.
- Notification for commercialization to the Brazilian Health Regulatory Agency (ANVISA) was completed, and the notification number was officially published on July 13, 2026. The product is now authorized for commercialization in Brazil, with product sales scheduled to commence in the fourth quarter of 2026. The product will be marketed under the brand name "epifilm."

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 have suspended development for this indication.
- In addition, the Company is currently evaluating the efficacy of SP-04 using a two-dimensional cell model of taxane-induced peripheral neuropathy at a domestic university laboratory.

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 tumor
- Territory under the Company's Rights: Japan
- In 2022, as the final results of the international Phase III clinical study (AGENT study) in colorectal cancer patients revealed that SP-05 did not achieve statistically significant outcomes in the primary or key secondary endpoints, the Company subsequently suspended development. In 2024, Isofol Medical AB, the originator and licensor of the product, decided to resume development of SP-05, and the Company likewise determined to restart development activities in Japan.
- Post-hoc analyses of the AGENT study confirmed that, in a subset of patients who strictly adhered to the study protocol, the SP-05 treatment group demonstrated higher efficacy than the leucovorin control group. A Phase Ib/II clinical study using an optimized dosing regimen is currently ongoing at Charité University Hospital, Berlin, Germany.

- In July 2026, the evaluation of the third dose level (300 mg/m²) in the dose-escalation Phase Ib part was completed without any dose-limiting toxicities. Based on the recommendation of the Safety Review Committee, enrollment in the cohort at the final dose level (500 mg/m²) has commenced. The Phase II part of the study in Germany is scheduled to commence in the second half of 2026.
- In Japan, which is within the Company's licensed territory, based on the results of the Phase Ib part, a separate Phase II clinical study with the same design as the above-mentioned Phase II part of the German study is scheduled to commence between the second half of fiscal 2026 and the beginning of 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 development candidates and technologies below are early-stage projects in the research or pre-clinical development stages. They have potential to become our next pipeline products, and we are working on research and development together with each partner company.

■ Nucleic acid drug candidate for peritoneal metastases

- In 2020, the Company entered into an agreement with GeneCare Research Institute Co., Ltd. ("GC"), a Japan-based biotech venture company holding exclusive negotiating rights (option rights) to in-license the latter's nucleic acid drug candidate RECQL1-siRNA and related technologies. The Company is currently conducting joint development with GC and will decide whether to exercise the option rights to in-license the drug candidate, considering progress in non-clinical studies and new formulation development.
- RECQL1-siRNA is a small interfering RNA (siRNA) molecule, a double-stranded nucleic acid drug discovered by GC based on technologies in-licensed from US-based Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), a world leader in RNA interference (RNAi) technologies. This siRNA is believed to have a novel mechanism of action to induce cell death by selectively suppressing the expression of the DNA repair enzyme helicase RECQL1, which is found to be overexpressed in cancer cells. In multiple pharmacological studies, the drug was shown to suppress the growth of various types of cancer and prolong survival in animal models of peritoneal dissemination associated with advanced-stage ovarian or gastric cancer.
- The Company and GC are currently conducting pharmacological studies and the development of new formulations to advance the novel siRNA sequences, which were discovered by the Ui-Tei Laboratory of the Graduate School of Science, the University of Tokyo, to the clinical development stage in collaboration with a domestic university laboratory. In addition, animal studies using a new lipid nanoparticle (LNP) formulation prototype targeting ovarian cancer are currently being conducted.

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 concluded a joint research and development agreement with EditForce, Inc., a biotech company originating from Kyushu University. For the Company, the initiative is a means of acquiring candidate products for long-term development. Specifically, it furthers the Company's plans to develop new gene therapy drugs in the field of oncology based on its core RNA editing technology.
- The Company is currently evaluating the applicability of the pentatricopeptide repeat (PPR) technology to Niemann–Pick disease, a rare hereditary and progressive lysosomal disorder characterized by abnormal lipid metabolism, which leads to the accumulation of lipids in the liver, spleen, and brain.

■ 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.
- The fundamental Q-body technology involves attaching a fluorescent dye to an antibody and quenching its fluorescence until binding to a target antigen, upon which the dye emits fluorescence. Thus, Q-bodies function as biosensors whose fluorescence intensity varies according to antigen concentration.
- This immunoassay technology is expected to simplify procedures and reduce costs compared to conventional immunoassays. HikariQ is engaged in joint R&D with other companies as well in its immunoassay business.
- In addition, a preliminary review is currently being conducted on the discovery and development of next-generation antibody drug conjugate (ADC) products using this technology, including the development of a prototype novel darinaparsin ADC based on Q-body technology.

■ Joint commercialization of functional fluorescent probe technology

- This project aims to evaluate the commercial potential of the technology prior to commencing joint research and development with Goryo Chemical Co., Ltd. In 2023, the Company entered into an agreement with Goryo Chemical, Inc. to evaluate and explore joint commercialization opportunities, including navigation drugs for cancer surgery using Goryo's fluorescent probe technology.
- As the first phase, both companies are currently conducting exploratory development and an evaluation of commercialization possibilities in Japan and the U.S. for GCP-006, a navigation drug targeting breast cancer.
- In July 2025, Goryo's new business, "Development of a performance evaluation system for newly synthesized trypsin and domestic manufacturing development of human gene sequence-type GMP trypsin," was selected for the Japanese Ministry of Economy, Trade and Industry's FY2025 Go-Tech Program. The Company serves as an advisor for this project.

3. Corporate information

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

- In the second quarter of the fiscal year ending December 31, 2026, the Company recorded revenue of JPY 8 million, mainly driven by sales of episil® (SP-03) products, and gross profit amounted to JPY 6 million. During the second quarter, shipment of Sancuso® products to MAAB and receipt of payment for product sales (USD 1,299,240) were completed. However, as certain documentation procedures associated with the change of the sales partner remained incomplete as of the end of the second quarter, revenue from these product sales is expected to be recognized in the third quarter.
- R&D expenses amounted to JPY 230 million, primarily reflecting cost reduction initiatives and evaluation of additional indications for DARVIAS® (SP-02), animal studies for SP-04, preparations for the clinical study of SP-05, and investments in new development candidates.
- Selling, general and administrative expenses amounted to JPY 347 million. As a result, operating loss amounted to JPY 570 million, and net loss amounted to JPY 579 million.

■ Major shareholders information

- As of the end of June 2026, according to the Company's shareholder registry, the largest shareholder was Nippon Kayaku Co., Ltd. (ownership ratio: 4.38%), the Japanese partner for DARVIAS®, and the second largest shareholder was Maruho Co., Ltd. (ownership ratio: 4.14%), the Japanese 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 contained in this press release is for informational purposes only and should not be considered as investment solicitation. Information about pharmaceuticals and medical devices (including products under development) is not provided for the purposes of advertising or medical advice. We do not have any obligation to update or revise any information in this press release, and any update or revision may occur anytime without notice.