

Sosei Heptares Operational Highlights and Consolidated Results for the Third Quarter and First Nine Months of 2023

Tokyo, Japan and Cambridge, UK, 10 November 2023 – Sosei Group Corporation (“Sosei Heptares” or “the Company”; TSE: 4565) provides an update on operational activities and reports its consolidated results for the third quarter and nine months ended 30 September 2023. The full report can be found by [clicking here](#).

Chris Cargill, President & CEO of Sosei Heptares, commented: “The third quarter has been an exciting and transformational period for the Group following the acquisition of Idorsia’s pharmaceutical business in Japan and Asia-Pacific (ex-China). The addition of an experienced, high-quality development and commercialization team and two potentially life-changing approved and late-stage assets complements extremely well our world-leading GPCR-targeted discovery and early development business in the UK, enabling us to become a fully integrated biopharmaceutical organization. Together, our enlarged Group can offer broad capabilities, an expanded pipeline addressing multiple therapeutic areas of unmet need, and a lean and agile business model capable of taking drugs from discovery to patients in Japan while progressing existing and initiating new partnerships globally. We are making good progress with the initial integration of these businesses.

“Operationally, we are also delighted to have fulfilled the commitment to file an NDA for daridorexant for approval in Japan as a new treatment for patients with insomnia. At the same time, we continue to build on our core activities that have resulted in the successful advancement of multiple new candidates into clinical studies and collaborative programs.

“We are confident that our bold strategy, actions and potential will position Sosei Heptares as a new and dynamic leader in the Japanese biopharma industry, delivering life-changing medicines to patients globally and allowing us to create significant value for all our key stakeholders.”

Operational Highlights for Q3 2023

- **Transformational acquisition of Idorsia’s pharmaceutical business in Japan and APAC (ex-China)** – achieves key strategic milestone to become a fully integrated biopharmaceutical company:
 - Adds complementary late-stage clinical development capability with profitable and fast-growing commercial operations in Japan.
 - Brings highly experienced team, with proven clinical development and commercial launch track record.
 - Lean, go-to-market commercial model, well positioned to scale rapidly to generate significant value from Japan and APAC (ex-China) geographic expansion.
 - Includes Japan and APAC (ex-China) rights to two life-changing medicines with significant growth potential (PIVLAZ® – approved for cerebral vasospasm, and

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daridorexant – Japan filing expected and delivered in Q4 2023 for insomnia) and exclusive options and selected rights to up to seven other products from Idorsia's clinical development pipeline.

- Purchase price of JPY65 billion is fully funded from existing cash (JPY25 billion) and new JPY40 billion long-term, low-rate corporate loan.
- **First subject dosed with HTL0048149 in Phase 1 Trial** – HTL'149 is a first-in-class GPR52 agonist designed by the Company as a once-daily oral treatment to address positive and negative symptoms and cognitive impairment in schizophrenia patients without the adverse effects typically associated with existing antipsychotic drugs.
- **First patient dosed with potential cancer immunotherapy HTL0039732 in Phase 1/2a clinical trial** – HTL'732 is an orally available small molecule EP4 antagonist for advanced solid tumors being evaluated under an agreement with Cancer Research UK.
- **Partner Neurocrine Biosciences initiated Phase 1 clinical study with NBI-1117570** – NBI-1117570 is an investigational, oral, muscarinic M1/M4 selective dual agonist developed utilizing the Group's SBDD platform and that may have the potential to treat neurological and neuropsychiatric conditions.

Post-period Events

- **New Drug Application submitted to the Japanese Pharmaceuticals and Medical Devices Agency for the approval of daridorexant (ACT541468), a novel dual orexin receptor antagonist, for the treatment of adult patients with insomnia** – In relation to the filing of this NDA, the Group will receive JPY 1.5 billion, which will be recognized as revenue in Q4 2023. If approved, daridorexant will be co-marketed in Japan by Sosei Group and Mochida Pharmaceutical Co., Ltd. ("Mochida") and Shionogi & Co. Ltd ("Shionogi"). Mochida and Shionogi entered into a sales partnership agreement in Japan for daridorexant on 1 November 2023.
- **Partner Pfizer entered a new oral small molecule GLP-1 receptor agonist into a Phase 1 clinical trial** – PF-06954522 was discovered by Pfizer scientists during a multi-target research collaboration in which Pfizer had access to Sosei Heptares' proprietary StaR® technology.
- **Collaboration with Verily progressing with launch of new discovery program** – new program established based on the successful validation and nomination of a GPCR target for immune-mediated diseases with an initial indication focus of inflammatory bowel diseases.
- **Collaboration expanded with PharmEnable Therapeutics** – expansion focused on driving drug discovery of novel small molecule drug candidates against a second neurological disease target.
- **US\$3.75 million milestone payment received from Genentech** – the discovery-based payment is related to progression of a potential first-in-class project targeting an undisclosed GPCR. Genentech will now be responsible for further development and commercialization of this potential new medicine.

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Note regarding the Idorsia transaction: the quarter ended 30 September 2023 (Q3 2023) is the first period in which the Group has consolidated the financial results of Idorsia's former Japanese and South Korean businesses.

Financial Highlights for the Nine-month Period ended 30 September 2023

- Revenue totalled JPY 5,474 million (US\$39.6 million*), a decrease of JPY 3,167 million (US\$27.9 million) vs. the prior corresponding period. The decrease is primarily due to the decrease in revenue related to upfront fees and milestone income due to signing no new partnership agreements and the occurrence of one milestone event in the current period vs. one upfront fee and three milestone events in the prior corresponding period, partially offset by the increase in pharmaceutical product sales due to the inclusion of Idorsia Pharmaceuticals Japan Ltd ("IPJ") in the scope of consolidation in July, which resulted in the addition of PIVLAZ® sales.
- R&D expenses totalled JPY 7,013 million (US\$50.8 million), an increase of JPY 1,390 million (US\$6.9 million) vs. the prior corresponding period. This increase reflects an increased investment in discovery activities, but also reflects the impact of the weaker Yen. JPY 358 million (US\$2.6 million) has been included for R&D expenses relating to IPJ and Idorsia Pharmaceuticals Korea Co., Ltd ("IPK").
- G&A expenses totalled JPY 6,012 million (US\$43.5 million), an increase of JPY 2,842 million (US\$18.7 million) vs. the prior corresponding period. This increase is primarily due to the inclusion of non-recurring M&A related costs. JPY 1,417 million (US\$10.3 million) has been included for G&A expenses relating to IPJ/IPK.
- Operating loss totalled JPY 7,992 million (US\$57.9 million) vs. an operating loss of JPY 615 million (US\$4.8 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.
- Loss before income tax totalled JPY 7,865 million (US\$57.0 million) vs. a loss before income tax of JPY 3,108 million (US\$24.3 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.
- Net loss for the nine-month period ended 30 September 2023 totalled JPY 6,985 million (US\$50.6 million) vs. a net loss of JPY 3,225 million (US\$25.2 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.
- Core operating loss** totalled JPY 3,920 million (US\$28.4 million) vs. a core operating profit of JPY 1,300 million (US\$10.2 million) in the prior corresponding period.
- Cash and cash equivalents as at 30 September 2023 amounted to JPY 42,386 million (US\$283.8 million) having decreased by JPY 24,171 million (US\$223.2 million) from the beginning of the year. This decrease was primarily due to the transaction with Idorsia.

*Convenience conversion to US\$ at the following rates: FY 2023: 1US\$ =138.09 JPY; FY 2022: 1US\$ =127.94 JPY; 30 Sep 2023: 1US\$ = 149.37 JPY; 31 Dec 2022: 1US\$ = 131.27 JPY

** Core operating profit / loss is an alternative performance measure which adjusts for material non-cash costs and one-off costs in order to provide insights into the recurring cash generation capability of the core business.

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About Sosei Heptares

Sosei Heptares is a fully integrated biopharmaceutical company focused on bringing life-changing medicines based on world-class science to patients globally. Our vision is to become one of Japan's global biopharmaceutical champions.

Our global business combines our world-leading GPCR-targeted StaR® technology, structure-based drug design and early development capabilities in the UK with a highly experienced clinical development capability and a commercial operation in Japan.

We are leveraging these capabilities to generate and advance a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology and inflammatory diseases. We intend to develop these opportunities for patients in Japan and globally both internally and through our partnerships with global biopharmaceutical companies and emerging technology companies.

Sosei Heptares operates from key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea).

"Sosei Heptares" is the corporate brand and trademark of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565). Sosei, Heptares, the logo and StaR® are trademarks of Sosei Group companies.

For more information, please visit <https://soseiheptares.com/>

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Enquiries

Sosei Heptares – Media and Investor Relations

Kentaro Tahara, VP Investor Relations and Corporate Strategy

Shinichiro Nishishita, VP Investor Relations, Head of Regulatory Disclosures

Maya Bennison, Communications Manager

+81 (0)3 5210 3399 | +44 (0)1223 949390 | IR@SoseiHeptares.com

MEDI STRAVA Consulting (for International Media)

Mark Swallow, Frazer Hall, Erica Hollingsworth

+44 (0)203 928 6900 | SoseiHeptares@medistrava.com

Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Sosei Group Corporation's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product

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initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.