

Sosei Heptares Operational Highlights and Consolidated Results for 12 Months ended 31 December 2023

Tokyo, Japan and Cambridge, UK, 13 February 2024 – Sosei Group Corporation (“Sosei Heptares” or “the Company”; TSE: 4565) provides an update on operational activities and reports its consolidated results for the 12 months ended 31 December 2023. The full report can be found by clicking [here](#).

Chris Cargill, President & CEO of Sosei Heptares, commented: “2023 has been a transformational year for Sosei Group and the progress made by our teams across all areas of the business has been exceptional. This progress is enabling the Group to accelerate its development in 2024 as an integrated, technology powered, commercial-stage biopharmaceutical company focused on cutting-edge science and delivering life-changing medicines for patients in Japan and globally.

“We continue to accelerate business integration following the acquisition of Idorsia Pharmaceuticals Japan Ltd (“IPJ”) and Idorsia Pharmaceuticals Korea Co., Ltd (“IPK”), which has brought an exciting new dimension to our Group including the potential for many strategic development and commercial opportunities. We embark on this next phase of our journey as a well-financed organization and with a clear vision to create value for all our stakeholders and I want to thank all our employees for their efforts in making this a reality.”

Operational Highlights for Q4 2023

- **Landmark investment of ~JPY8 billion (~USD54m) into Sosei Group from new OPF1 fund operated by JIC Venture Growth Investments Co., Ltd., an affiliate of Japan Investment Corporation** – in conjunction with a share offering and convertible bond restructuring to finance the Group’s strategic growth initiatives; to extend the maturity profile of its debt; and further strengthen its financial base.
- **Marketing approval for PIVLAZ® in South Korea** – for the prevention of cerebral vasospasm and related conditions after aneurysmal subarachnoid hemorrhage (“aSAH”) securing.
- **New Drug Application submitted in Japan for the approval of daridorexant, a novel dual orexin receptor antagonist, for the treatment of adult patients with insomnia** – in relation to the submission, the Group received JPY 1.5 billion, which has been recognized as revenue in Q4 2023.
- **Partner Neurocrine confirmed its plans to evaluate two new muscarinic agonist candidates in Phase 1 studies** – both NBI-1117569 (a muscarinic M4-preferring agonist) and NBI-1117567 (a muscarinic M1-preferring agonist) are oral compounds that may have the potential to treat neurological and neuropsychiatric conditions. A Phase 1 study of NBI-1117569 has begun and a Phase 1 study of NBI-1117567 is expected to begin in 2024.
- **Partner Pfizer entered a new oral small molecule GLP-1 receptor agonist into a Phase 1 clinical trial targeting metabolic diseases** – PF-06954522 was discovered by Pfizer

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scientists during a multi-target research collaboration in which Pfizer had access to Sosei Heptares' StaR® technology.

- **Discussions underway with GSK to regain full ownership of GSK43814061, a clinic-ready, first-in-class, oral GPR35 agonist targeting Inflammatory Bowel Diseases ("IBD")** – upon regaining ownership, the Group expects to proceed with a planned UK Phase 1 trial of GSK43814061 while determining the optimal strategy for the further clinical development and/or re-partnering of the program.
- **US\$3.75 million milestone payment received from partner 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.
- **Strong progress in collaborations with leading technology companies**
 - **Kallyope** – identification, validation and nomination of a first GPCR target to enter a therapeutic discovery program for gastrointestinal diseases,
 - **Verily** – launching a new discovery program based on the successful validation and nomination of a GPCR target for immune-mediated diseases with an initial indication focus of IBD, and
 - **PharmEnable Therapeutics** – expansion of a collaboration to drive discovery of novel small molecule drug candidates against a second neurological disease target.

Operational Highlights for Full Year 2023

- **Transformational acquisition of Idorsia's pharmaceutical business in Japan and APAC** – 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 geographic expansion.
 - Includes Japan and APAC (ex-China) rights to two medicines with significant growth potential (PIVLAZ®) and daridorexant, as well as 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 wholly owned 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 cancer immunotherapy candidate HTL0039732 in Phase 1/2a trial** – HTL'732 is an orally available small molecule EP4 antagonist for advanced solid tumors being evaluated under an agreement with Cancer Research UK.

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- **Partner Neurocrine Biosciences initiated Phase 1 clinical study with NBI-1117570** – an investigational, oral, muscarinic M1/M4 selective dual agonist that may have the potential to treat neurological and neuropsychiatric conditions.
- **Partner Tempero Bio received FDA clearance to advance clinical development of TMP-301 for alcohol and substance use disorders** – TMP-301 (formerly HTL0014242) is a selective, orally available mGluR5 negative allosteric modulator (NAM) candidate discovered by Sosei Heptares and out-licensed to Tempero Bio.
- **Sosei Group's share listing elevated to the Tokyo Stock Exchange Prime Market** – shortly after, Sosei Group shares were included in the Tokyo Stock Price Index (TOPIX).
- **Changes to Board and Executive Management team** – Ms. Eiko Tomita, a highly experienced pharmaceutical executive, was elected as an Independent External Director. Ms. Candelle Chong was promoted to Executive Vice President and Chief of Staff.

Post-period Highlights

- **Appointment of Chief Operating Officer** – Mr. Toshihiro Maeda was appointed to this newly created role at Sosei Heptares to lead the post-acquisition integration of IPJ, and global technical operations, including manufacturing, supply chain and quality assurance, for the enlarged business in Japan and the Asia-Pacific region.

Financial Highlights

- Revenue totalled JPY 12,766 million (US\$90.8 million*), a decrease of JPY 2,803 million (US\$27.7 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 four milestone events in the current period vs. two upfront fee and five milestone events in the prior corresponding period, partially offset by the increase in pharmaceutical product sales due to the inclusion of IPJ in the scope of consolidation in July 2023, which resulted in the addition of PIVLAZ[®] sales.
- R&D expenses totalled JPY 10,075 million (US\$71.7 million), an increase of JPY 2,621 million (US\$14.9 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 881 million (US\$6.3 million) has been included for R&D expenses relating to IPJ and IPK.
- G&A expenses totalled JPY 9,965 million (US\$70.9 million), an increase of JPY 5,588 million (US\$37.6 million) vs. the prior corresponding period. This increase is primarily due to the inclusion of non-recurring M&A related costs. JPY 3,755 million (US\$26.7 million) has been included for G&A expenses relating to IPJ/IPK.
- Operating loss totalled JPY 9,526 million (US\$67.8 million) vs. an operating profit of JPY 3,436 million (US\$26.2 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.

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- Loss before income tax totalled JPY 10,680 million (US\$76.0 million) vs. a profit before income tax of JPY 1,078 million (US\$8.2 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.
- Net loss for the year ended 31 December 2023 totalled JPY 7,193 million (US\$51.2 million) vs. a net profit of JPY 382 million (US\$2.9 million) in the prior corresponding period. This increase reflects the combined effect of all the movements explained above.
- Core operating loss** totalled JPY 3,076 million (US\$21.9 million) vs. a core operating profit of JPY 5,856 million (US\$44.6 million) in the prior corresponding period.
- Cash and cash equivalents as at 31 December 2023 amounted to JPY 49,065 million (US\$347.9 million) having decreased by JPY 17,492 million (US\$159.1 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\$ =140.53 JPY; FY 2022: 1US\$ =131.30 JPY; 31 Dec 2023: 1US\$ = 141.03 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.

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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 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.