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Sosei Heptares Operational Highlights and Consolidated Results for 12 Months ended 31 December 2022

Tokyo, Japan and Cambridge, UK, 14 February 2023 – Sosei Group Corporation (“the Company”; TSE: 4565), the world leader in G protein-coupled receptor (GPCR) focused structure-based drug design (SBDD) and development, provides an update on operational activities and reports its consolidated results for the 12 months ended 31 December 2022. The full report can be found [here](#).

Chris Cargill, President & CEO of Sosei Heptares, commented: “2022 was a very important and successful year for Sosei Heptares as our newly appointed leadership team set about evolving and implementing a clear strategy to accelerate the growth and development of the Company. This strategy is based on four key pillars: (1) to extend and enhance the competitive advantages of our in-house GPCR drug discovery platform through internal innovation and collaboration; (2) to drive forward existing partnerships with global biopharma companies and initiate new high-value partnerships to ensure the continued flow of revenues; (3) to transform how we do R&D through a more focused, program-centric operational model that leverages enhanced translational medicine capabilities to improve productivity, value and success; and (4) to build out an agile, scalable and effective clinical development and commercialization business in Japan to deliver new medicines to patients in this market.

“Overall, the progress we have made in 2022 has been exceptional and I would like to thank the teams in Japan and in the UK for their dedication and hard work. We enter 2023 well positioned and well financed to progress our strategy across all areas, and with a clear vision to build a disruptive commercial-stage biopharmaceutical company making a difference for patients worldwide.”

Operational Highlights for Q4 2022

- **New multi-target collaboration with Lilly targeting diabetes and metabolic diseases** – Sosei Heptares will focus its discovery efforts on GPCR targets nominated by Lilly to deliver novel target-selective hit candidates for further development and commercialization by Lilly. Sosei Heptares received an upfront payment of US\$37 million and is eligible to receive milestones totalling up to US\$694 million, plus tiered royalties on global sales.
- **US\$10 million clinical development milestone payment received from Pfizer** – for dosing of the first subject in a Phase 2 trial with PF-07081532, a once-daily, oral small molecule GLP-1 receptor agonist in development for the treatment of Type 2 diabetes and obesity. PF-07081532 was discovered by Pfizer during a multi-target research collaboration in which its scientists had access to Sosei Heptares’ StaR® technology.
- **US\$10 million R&D milestone payment received from AbbVie** – for progress made under its 2020 discovery collaboration targeting inflammatory and autoimmune diseases.

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- **R&D agreement with the University of Oxford and KU Leuven** – to apply the innovative technologies and research capabilities of the respective groups to identify, validate and prioritize key GPCRs driving gastrointestinal and immune disorders, including inflammatory bowel disease (IBD), as targets for SBDD.

Operational Highlights for Full Year 2022

- **New senior leadership team** appointed to drive the Company through its next phase of evolution – building on its existing strengths with the aim of establishing an agile, best-in-class drug discovery and development organization.
- **Transforming inhouse R&D to a program-centric operational model** – through strategic collaboration with specialist consulting group Weatherden – to enhance discovery and translational medicine capabilities and accelerate the prioritization and progression of multiple pipeline programs through Phase 1b/2a trials to establish clinical proof-of-concept, a key milestone for value creation to support partnering and growth opportunities.
- **Expansion of UK R&D operations to a second site in Cambridge, UK** – driven by the Company’s growth and strategy to become a multi-program, early clinical stage business and a partner-of-choice for leading biopharmaceutical companies.
- **New multi-target collaboration with AbbVie targeting neurological diseases** – Sosei Heptares received a US\$40 million upfront fee and is eligible to receive up to US\$40 million in near-term research milestone payments expected over the next three years, as well as further potential option, development and commercial milestones totalling up to US\$1.2 billion, plus tiered royalties on global sales.
- **US\$30 million clinical development milestone payment received from Neurocrine Biosciences** – for the advancement of NBI-1117568 (formerly HTL-0016878) into Phase 2 trials. NBI-1117568 is an investigational, muscarinic M4 selective acetylcholine receptor agonist in development for the treatment of adults with schizophrenia.
- **Further R&D milestones achieved and payments received** – from progress in partnerships with Takeda and Genentech.
- **Clinical development agreement with Cancer Research UK** – to advance Sosei Heptares’ immunotherapy candidate HTL0039732 into a Phase 1/2a trial. HTL0039732 is a novel selective EP4 antagonist with potential to treat a wide range of cancers in combination with other immunotherapies. CRUK will sponsor, design and conduct the trial.
- **Research collaboration with Verily** – to leverage the complementary capabilities of Verily’s immune profiling and Sosei Heptares’ SBDD platform to identify novel targets for drug discovery against immune-mediated diseases.
- **Research collaboration with Kallyope** – to leverage Sosei Heptares’ GPCR Diversified Compound Library and GPCR expertise with Kallyope’s gut-brain axis platform to identify and validate novel gastrointestinal GPCR targets for drug discovery.

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Post-period Highlights

- Sosei Heptares' 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. Tempero Bio was created in 2020 in collaboration with Sosei Heptares to advance the clinical development of a portfolio of mGluR5 NAMs, including TMP-301, targeting substance use disorders and anxiety.

Financial Highlights for the 12-month Period ended 31 December 2022

- Revenue totalled JPY 15,569 million (US\$118.6 million*), a decrease of JPY 2,143 million (US\$42.2 million) vs. the prior year. The decrease primarily reflects the inclusion in the prior year of a substantial upfront fee from Neurocrine Biosciences in the amount of JPY 11,408 million (USD 100 million). This compares with upfront fee revenue recognised at deal inception totalling JPY 4,666 million (USD 35 million) from the signing of two new collaborations (AbbVie Neurology and Lilly) in 2022. Revenue in 2022 also benefitted from a rise in milestone income recognised upon the achievement of several milestone events.
- R&D expenses totalled JPY 7,454 million (US\$56.8 million), an increase of JPY 1,523 million (US\$2.9 million) vs. the prior year. The increase is primarily due to increased investment in our in-house discovery and early development programs, including the cost of a restructuring program designed to accelerate the development of novel medicines. Costs also increased due to inflation and the impact of the weaker Yen.
- G&A expenses totalled JPY 4,377 million (US\$33.3 million), an increase of JPY 437 million (a decrease of US\$2.4 million) vs. the prior year. The increase (in JPY) is primarily due to cost of a restructuring program designed to accelerate the development of novel medicines, cost inflation and the impact of the weaker Yen.
- Operating profit totalled JPY 3,436 million (US\$26.2 million), a decrease of JPY 339 million (US\$8.1 million) vs. the prior year. The main reasons for the decrease in the operating profit are the decrease in revenue and increase in R&D expenditure, for the reasons stated above.
- Net profit before tax totalled JPY 1,078 million (US\$8.2 million), an increase of JPY 645 million (US\$4.3 million) vs. the prior year. The increase in net profit before tax is the result of a decrease in net finance costs associated with a non-recurring event in the prior year. This was due to a substantial contingent charge being recorded relating to the Neurocrine Biosciences licensing transaction. This increase was partially offset by an impairment loss on investments accounted for using the equity method totalling JPY 1,836 million. This was due to a decrease in the estimated fair value of the shareholding in MiNA Therapeutics.
- Net profit after tax totalled JPY 382 million (US\$2.9 million), a decrease of JPY 635 million (US\$6.3 million) vs. the prior year. The decrease reflects the combined effects of all of the movements explained above plus a higher tax charge for the year.

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- Core operating profit** totalled JPY 5,856 million (US\$44.6 million), a decrease of JPY 3,048 million (US\$36.2 million) vs. the prior year. The main reasons for the decrease are the reduction in revenues in 2022 as explained above, and an increase in investment in R&D in line with the Group's growth strategy.
- Cash and cash equivalents as at 31 December 2022 increased by JPY 6,470 million from the beginning of the year and amounted to JPY 66,557 million.

**Convenience conversion to US\$ at the following rates: FY 2022: 1US\$ =131.30 JPY; FY 2021: 1US\$ =110.16 JPY; 31 Dec 2022: 1US\$ = 131.27 JPY; 31 Dec 2021: 1US\$ = 115.08 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

We are an international biopharmaceutical group focused on the discovery and early development of new medicines originating from our proprietary GPCR-targeted StaR[®] technology and structure-based drug design platform capabilities. We are advancing a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology, and inflammatory diseases.

We have established partnerships with some of the world's leading pharmaceutical companies and multiple emerging technology companies, including AbbVie, AstraZeneca, Genentech (Roche), GSK, Kallyope, Lilly, Neurocrine Biosciences, Novartis, Pfizer, Takeda and Verily. Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in Cambridge, UK.

"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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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.