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Sosei Heptares Operational Highlights and Consolidated Results for the Second Quarter and First Half of 2023

Tokyo, Japan and Cambridge, UK, 4 August 2023 – Sosei Group Corporation (“the Company”; TSE: 4565) provides an update on operational activities and reports its consolidated results for the second quarter and first half ended 30 June 2023. The full report can be found by [clicking here](#).

Chris Cargill, President & CEO of Sosei Heptares, commented: “We begin the second half of 2023 as a much enlarged, transformed and energized organization with a clear strategy for success, following the completion of the fully funded acquisition of Idorsia’s pharmaceutical business in Japan and Asia-Pacific (ex-China).

“We are confident that the addition of this business – bringing an experienced team with extensive development capabilities and commercial expertise, along with selected product rights that include PIVLAZ[®], an approved and fast-growing product, and daridorexant, for which J-NDA filing is expected in 2H 2023 – creates the ideal platform to deliver our revenue and growth goals in Japan and Asia Pacific (ex-China).

“The acquired operation is also highly complementary to our world-leading GPCR-targeted discovery and early development business in the UK, allowing us to become a fully integrated organization, with the broad capabilities, expanded pipeline and lean and agile business model, capable of taking drugs from discovery to patients in Japan while opening new partnering opportunities globally.

“Our immediate focus is to integrate the businesses to ensure continued operational efficiency so that we can progress our expanded internal discovery and development programs, support our multiple partnered programs, and develop our commercial activities in Asia Pacific (ex-China).

“We are confident that this integration will result in Sosei Heptares being well positioned to achieve its goal of becoming a new and dynamic leader in the Japanese biopharma industry, delivering life-changing medicines to patients globally and allowing us to create significant value to all our key stakeholders.”

Operational Highlights for H1 2023

- On 15 March 2023, Sosei Group’s share listing was elevated to the Prime Market segment of the Tokyo Stock Exchange from the Growth Market segment – Further, on 27 April 2023, Sosei Group shares were included in the Tokyo Stock Price Index (TOPIX), an important stock market index that tracks all domestic companies mainly on the Prime market segment.
- Sosei Heptares’ partner, Tempero Bio, received FDA clearance to advance clinical development of TMP-301 for alcohol and substance use disorders (January) – TMP-301



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(formerly HTL0014242) is a selective, orally available mGluR5 negative allosteric modulator (NAM) candidate discovered by Sosei Heptares and out-licensed to Tempero.

- **Centessa Pharmaceuticals nominated ORX750 as its product candidate with potential to be a best-in-class therapy for narcolepsy and other sleep disorders (March)** – ORX750 is an orally administered, selective orexin receptor-2 (OX2R) agonist developed using Sosei Heptares' platform, and currently in preclinical development and undergoing IND-enabling activities.
- **Pfizer announced its decision to prioritize the development of danuglipron over lotiglipron for the treatment of diabetes and obesity (June)** – as a result, Pfizer discontinued the development of lotiglipron, a novel and orally available GLP-1 receptor agonist discovered and developed by Pfizer during a multi-target research collaboration with Sosei Heptares. Sosei Heptares will explore next steps with Pfizer for the future development of lotiglipron.
- **Changes to the Board and Executive Management Team (March)** – Eiko Tomita (VP, Global Regulatory Affairs at Bristol Myers Squibb) was elected to the Board of Directors and Candelle Chong was promoted to EVP and Chief of Staff (previously Senior Vice President, Corporate Strategy) at the Annual Shareholder's Meeting and the subsequent Board of Directors meeting held on 23 March 2023.

Post-period Events

- **Transformational acquisition of Idorsia's pharmaceutical business in Japan and APAC (ex-China) (July)** – 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, led by Dr. Satoshi Tanaka.
 - 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 daridorexant – Japan filing expected in H2 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 from Mizuho Bank.
 - Transaction is expected to be cash-flow positive in first full calendar year.
- **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.

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Note regarding the Idorsia transaction: the Group's recent transaction with Idorsia Limited occurred after the 30 June 2023 balance sheet date, and therefore the forthcoming quarterly period ending 30 September 2023 (Q3 2023) will be the first period in which the Group consolidates the financial results of Idorsia's former Japanese business. For reference, on 25 July 2023, Idorsia Limited reported net sales of PIVLAZ® in Japan for the six-month period ended 30 June 2023 of CHF32 million, an increase of CHF21 million (or +184%) vs. the prior corresponding period. As a result of the transaction, the Group's pro forma Cash and Cash Equivalents as at 31 July 2023 amounted to JPY 43,507 million (US\$309 million), having decreased by JPY 22,091 million (US\$156 million) from 30 June 2023 as a result of partially funding the transaction.

Financial Highlights for the Six-month Period ended 30 June 2023

- Revenue totalled JPY 2,146 million (US\$15.9 million*), a decrease of JPY 311 million (US\$4.1 million) vs. the prior corresponding period. The decrease is primarily due to the decrease in revenue related to royalties and other revenue, partially offset by the increase in revenue related to upfront fees and milestone income due to larger releases of deferred revenue.
- R&D expenses totalled JPY 4,039 million (US\$30.0 million), an increase of JPY 341 million (a decrease of US\$0.1 million) vs. the prior corresponding period. This increase reflects an increased investment in discovery activities, but also reflects the impact of the weaker Yen.
- G&A expenses totalled JPY 2,571 million (US\$19.1 million), an increase of JPY 306 million (US\$0.6 million) vs. the prior corresponding period. This was primarily due to professional advisory fees relating to the acquisition of Idorsia Limited's pharmaceuticals business in Japan and APAC (ex-China), which completed on July 20, 2023.
- Operating loss totalled JPY 4,168 million (US\$30.9 million) vs. an operating loss of JPY 3,804 million (US\$31.0 million) in the prior corresponding period. This increase reflects the combined effect of all of the movements explained above.
- Loss before income tax totalled JPY 3,760 million (US\$27.9 million) vs. a loss before income tax of JPY 4,282 million (US\$34.9 million) in the prior corresponding period. This decrease reflects the combined effect of all of the movements explained above, together with higher interest income (as a result of higher UK interest rates) and a reduction in cost relating to the cessation of equity accounting for the Group's investment in MiNA.
- Net loss for the 6-month period ended 30 June 2023 totalled JPY 2,060 million (US\$15.3 million) vs. a net loss of JPY 3,538 million (US\$28.8 million) in the prior corresponding period. This decrease reflects the combined effect of all of the movements explained above combined with a higher income tax benefit.
- Core operating loss** totalled JPY 2,720 million (US\$20.2 million) vs. a core operating loss of JPY 2,378 million (US\$19.4 million) in the prior corresponding period.
- Cash and cash equivalents as at 30 June 2023 amounted to JPY 65,598 million (US\$453.1 million) having decreased by JPY 959 million (US\$53.9 million) from the beginning of the year.

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**Convenience conversion to US\$ at the following rates: FY 2023: 1US\$ =134.82 JPY; FY 2022: 1US\$ =122.83 JPY; 30 Jun 2023: 1US\$ = 144.78 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.

Sosei Heptares has a leading development capability and a profitable and growing commercial operation in Japan, which it intends to expand into additional selected markets in the Asia-Pacific region.

Sosei Heptares is advancing a broad and deep pipeline of novel medicines created using its world-leading GPCR-targeted StaR[®] technology and structure-based drug design platform across multiple therapeutic areas, including neurology, immunology, gastroenterology, and inflammatory diseases.

In addition, we have leveraged our unique discovery and development capabilities to establish multiple value-generating partnerships with world-leading biopharmaceutical companies, including AbbVie, Genentech (Roche), GSK, Lilly, Neurocrine Biosciences, Novartis, Pfizer, Sanofi and Takeda.

Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in London and Cambridge, UK.

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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.