

Nxera Pharma Operational Highlights and Consolidated Results for the Second Quarter and First Half 2024

Tokyo, Japan and Cambridge, UK, 9 August 2024 – Nxera Pharma (“the Company” or “Nxera”; TSE: 4565) provides an update on operational activities and reports its consolidated results for the second quarter and first half ended 30 June 2024. The full report can be found [here](#).

Chris Cargill, President and CEO of Nxera, commented: “The reception we have received to our new name, branding and evolved strategy from all our stakeholders has been fantastic. In transitioning from Sosei Heptares to Nxera Pharma, we are united under a single identity with a clear purpose to become a leading technology driven biopharmaceutical company bringing new medicines to patients in Japan and globally.

“In Japan, we have made good progress building sales for PIVLAZ® alongside preparing for its commercialization in South Korea, with launch expected in 2025. Similarly, our preparations to commercialize daridorexant in Japan are progressing well in anticipation of a positive regulatory decision later this year.

“In addition, throughout 2024, we have continued to advance our internal programs into clinical trials, and to support the progress of our partnered programs through multiple preclinical and clinical development milestones, with further data and progress anticipated in the third quarter of 2024 and beyond. These are programs that our R&D team and powerful NxWave™ discovery platform have played a major role in creating, further reinforcing our position as the partner of choice for GPCR-targeted drug design, while generating significant value in terms of realised and future potential revenues.

“Overall, it is a very exciting time for Nxera, and with multiple important commercialization and development milestones anticipated in the near and medium term, we are confident that we have the right strategy to deliver success and value for our stakeholders as we seek to build a globally competitive next-generation biopharma company.”

Operational Highlights for Q2 2024

Corporate highlights

- Nxera Pharma, the new name for Sosei Heptares, came into effect on 1 April 2024 along with the launch of a new corporate brand and identity designed to capture the Group’s ambition to be at the forefront of the next era of biopharmaceuticals and medicine
- Joined the World Orphan Drug Alliance (WODA) to represent WODA in Japan and South Korea
 - Through WODA and its global networks, Nxera will gain access to a pipeline of novel medicines targeting rare or orphan diseases as potential licensing opportunities (with no obligation) for its late clinical stage and commercialization operations in these regions
- Senior team strengthened with appointment of experienced senior strategy consultant Patrick Branch as Head of Business Development for Japan and APAC

Progress with in-house programs

- Exclusive supply and distribution agreement with Handok for PIVLAZ™ (clazosentan sodium) 150 mg in South Korea
- PIVLAZ™ is the first drug approved in South Korea for the prevention of Cerebral Vasospasm in patients with Aneurysmal Subarachnoid Hemorrhage (aSAH) and is expected to become commercially available in South Korea in early 2025
- Nxera and PrecisionLife announced an expansion of their 2022 strategic R&D partnership into auto-immune disorders with the potential to identify new drug targets and subsequently potential precision targeted therapies for complex, chronic conditions.

Progress with partnered programs

- US\$15 million payment from Neurocrine Biosciences triggered by successful development progress of partnered schizophrenia candidate NBI-1117568
 - NBI-1117568 is an oral, selective muscarinic M4 receptor agonist advancing through Phase 2 clinical development under a multi-program collaboration
 - Successful completion of long-term preclinical toxicity program supports safe, chronic dosing of NBI-1117568 in future clinical trials
 - Topline clinical results from Neurocrine's Phase 2 study are expected in Q3 2024
- Neurocrine also announced that it had initiated its Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of NBI-1117567 in healthy adult participants
 - NBI-1117567 is an investigational, oral, M1 preferring agonist discovered by the Group and licensed to Neurocrine that may have the potential to treat symptoms of cognition in patients with neurological and neuropsychiatric conditions
- First R&D milestone reached under Nxera's multi-target discovery collaboration with AbbVie, resulting in a payment of US\$10 million to the Company
 - Collaboration aims to leverage Nxera's NxWave™ platform to discover, develop and commercialize new medicines targeting novel GPCR targets associated with neurological disease
- US\$4.6 million in milestone payments received from Centessa Pharmaceuticals following approval of an Investigational New Drug (IND) application for ORX750 and its progression into a Phase 1 clinical trial
 - ORX750 is an investigational, orally administered, highly potent and selective orexin receptor 2 (OX2R) agonist designed utilizing Nxera technology to directly target orexin neuron loss in narcolepsy and other sleep-wake disorders.

Financial Highlights for the Six-month Period ended 30 June 2024

- Revenue totalled JPY 12,720 million (US\$83.6 million*), an increase of JPY 10,574 million (US\$67.7 million) vs. the prior corresponding period. The increase was primarily due to the inclusion of Nxera Pharma Japan Co., Ltd. ("NPJ") in the scope of consolidation from July 2023, which resulted in the inclusion of PIVLAZ® sales.
- R&D expenses totalled JPY 5,487 million (US\$36.1 million), an increase of JPY 1,448 million (US\$6.1 million) vs. the prior corresponding period. This increase primarily reflects an increased investment in discovery activities, but also reflects the impact of the weaker Yen. JPY 813 million (US\$5.3 million) has been included for R&D expenses relating to NPJ/Nxera Pharma Korea Co., Ltd. ("NPK").
- G&A expenses totalled JPY 8,022 million (US\$52.8 million), an increase of JPY 5,451 million (US\$33.7 million) vs. the prior corresponding period. This increase was primarily due to incremental spend on personnel and professional fees to strengthen organizational capabilities, as well as the cost of

integrating IT systems and unifying the Group under the Nxera Pharma brand. JPY 4,740 million (US\$31.2 million) has been included for G&A expenses relating to the NPJ/NPK businesses, including an amortization charge on Idorsia related intangible assets.

- Operating loss totalled JPY 3,654 million (US\$24.0 million) vs. an operating loss of JPY 4,168 million (US\$30.9 million) in the prior corresponding period. This decrease reflects the combined effect of all movements explained above.
- Loss before income tax totalled JPY 3,158 million (US\$20.8 million) vs. a loss before income tax of JPY 3,760 million (US\$27.9 million) in the prior corresponding period. This decrease reflects the combined effect of all movements explained above.
- Net loss for the six-month period ended 30 June 2024 totalled JPY 4,703 million (US\$30.9 million) vs. a net loss of JPY 2,060 million (US\$15.3 million) in the prior corresponding period. This increase reflects the combined effect of all movements explained above.
- Core operating profit** totalled JPY 1,176 million (US\$7.7 million) vs. a core operating loss of JPY 2,720 million (US\$20.2 million) in the prior corresponding period.
- Cash and cash equivalents as at 30 June 2024 amounted to JPY 50,984 million (US\$316.9 million) having increased by JPY 1,919 million (decreased by US\$31.0 million) from the beginning of the year.

*Convenience conversion to US\$ at the following rates: FY 2024: 1US\$ = 152.12 JPY; FY 2023: 1US\$ = 134.82 JPY; 30 Jun 2024: 1US\$ = 160.91 JPY; 31 Dec 2023: 1US\$ = 141.03 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 Nxera Pharma

Nxera Pharma (formerly Sosei Heptares) is a technology powered biopharma company, in pursuit of new specialty medicines to improve the lives of patients with unmet needs in Japan and globally.

In addition to several products being commercialized in Japan, we are advancing an extensive pipeline of over 30 active programs from discovery through to late clinical stage internally and in partnership with leading pharma and biotech companies. This pipeline is focused on addressing major unmet needs in some of the fastest-growing areas of medicine across neurology, GI and immunology, metabolic disorders and rare diseases, and leverages the power of our unique and industry leading GPCR-targeted structure-based drug discovery “NxWave™” platform to provide a sustainable source of best- or first-in-class candidates.

Nxera employs over 350 talented people at key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea) and is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit www.nxera.life

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Enquiries:

Nxera – 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@Nxera.life

MEDiSTRAVA Consulting (for International Media)

Mark Swallow, Frazer Hall, Erica Hollingsworth
+44 (0)203 928 6900 | Nxera@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 Nxera Pharma Group'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.