Nxera Pharma Operational Highlights and Consolidated Results for the Third Quarter and First Nine Months of 2024

Tokyo, Japan and Cambridge, UK, 1 November 2024 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) – formerly known as Sosei Group or Sosei Heptares – provides an update on operational activities and reports its consolidated results for the third quarter and nine months ended on 30 September 2024. The full report can be viewed here.

Chris Cargill, President & CEO of Nxera, commented: "The third quarter of 2024 has seen Nxera reach two important product development milestones. First, in September, we received approval in Japan for QUVIVIQ™ for the treatment of adult patients with insomnia and are working towards making this new treatment available to patients as soon as possible under a new partnership with Shionogi. This achievement is a great example of Nxera's capabilities and ambitions in Japan and also reinforces our commitment to addressing critical health needs in the sleep disorder space. We believe that this therapy will make a meaningful difference in the lives of those struggling with insomnia.

"We were also thrilled by the positive Phase 2 data reported by our partner Neurocrine Biosciences for NBI-1117568 in schizophrenia and their commitment to advance this candidate into Phase 3 trials in 2025. We believe the clinical data highlight the competitive profile of NBI-1117568 and validate the power of our NxWave™ discovery platform to deliver differentiated molecules that modulate important disease targets.

"We look forward to reporting progress on these and other programs in our inhouse and partnered pipeline over future months as we continue our mission to bring innovative therapies to patients in Japan and around the world."

Operational Highlights for Q3 2024

- **Approval of QUVIVIQ™ (daridorexant) 25 and 50 mg by the Ministry of Health, Labour and Welfare of Japan ("MHLW") for the treatment of adult patients with Insomnia**
  - QUVIVIQ™ is a novel dual orexin receptor agonist that was successfully developed through a robust Phase 3 trial by Nxera Pharma Japan Co., Ltd. ("NPJ").
  - Plans are underway to make QUVIVIQ available as soon as possible to insomnia patients in Japan.

- **Partner Neurocrine Biosciences announced positive Phase 2 data for Schizophrenia candidate NBI-1117568**
  - NBI-'568 is a first-in-class, orally active, highly selective investigational M4 agonist, developed using Nxera's NxWave™ platform and licensed to Neurocrine.
  - Neurocrine's Phase 2 study met its primary endpoints, supporting its plans to advance NBI-'568 into Phase 3 trials in early 2025, and triggering a $35 million milestone payment to Nxera.

- **Partner Centessa announced positive interim Phase 1 data with ORX750 in acutely sleep-deprived healthy volunteers**
  - ORX750 is an investigational, orally administered, highly potent and selective orexin receptor 2 agonist, designed using Nxera technology to target the underlying pathophysiology of

orexin neuron loss in narcolepsy type 1 and other sleep-wake disorders.
    - Centessa stated it plans to advance ORX750 into Phase 2 studies before the end of 2024.

Post-period Events

- **New commercial partnership with Shionogi for QUVIVIQ™ in Japan**
    - Under the agreement, Nxera will be responsible for providing drug product for the Japanese market, and Shionogi will be exclusively responsible for distribution and sales in Japan.

- **Experienced Pharma Executive Makoto Sugita, M.D., Ph.D., MBA, Appointed as Chief Medical Officer and President of NPJ**
    - Dr. Sugita was formerly Vice President, Head of R&D for Bristol Myers Squibb in Japan – he brings nearly 20 years' experience in R&D and commercial roles working within the Japanese businesses of global pharmaceutical companies.

Financial Highlights for the Nine-month Period ended 30 September 2024

- Revenue totalled JPY 21,983 million (US$145.5 million*), an increase of JPY 16,509 million (US$105.8 million) vs. the prior corresponding period. This increase was primarily due to the inclusion of five development milestones and one upfront fee (vs. one milestone in the prior corresponding period), as well as the inclusion of NPJ in the scope of consolidation from July 2023, which resulted in the inclusion of a full nine months of PIVLAZ® sales in the current period.
- R&D expenses totalled JPY 8,517 million (US$56.4 million), an increase of JPY 1,504 million (US$5.6 million) vs. the prior corresponding period. This increase was primarily due to the inclusion of a full nine months of R&D expenditure by NPJ/ Nxera Pharma Korea Co., Ltd. ("NPK") in the current period, as well as an increased investment in UK R&D and the impact of the weaker Yen. JPY 1,160 million (US$7.7 million) has been included for R&D expenses relating to NPJ/NPK.
- SG&A expenses totalled JPY 11,717 million (US$77.5 million), an increase of JPY 5,705 million (US$34.0 million) vs. the prior corresponding period. This increase was primarily due to the inclusion of a full nine months of SG&A expenditure by NPJ/NPK in the current period as well as incremental spend on personnel and professional fees to strengthen organizational capabilities, the cost of integrating IT systems and unifying the Group under the Nxera Pharma brand. JPY 6,757 million (US$44.7 million) has been included for SG&A expenses relating to the NPJ/NPK businesses, including an amortization charge on Idorsia related intangible assets.
- Operating loss totalled JPY 2,846 million (US$18.8 million) vs. an operating loss of JPY 7,992 million (US$57.9 million) in the prior corresponding period. This decrease reflects the combined effect of all movements explained above.
- Loss before income tax totalled JPY 2,293 million (US$15.2 million) vs. a loss before income tax of JPY 7,865 million (US$57.0 million) in the prior corresponding period. This decrease reflects the combined effect of all movements explained above.
- Net loss for the nine month period ended 30 September 2024 totalled JPY 3,503 million (US$23.2 million) vs. a net loss of JPY 6,985 million (US$50.6 million) in the prior corresponding period. This improvement reflects the combined effect of all movements explained above.
- Core operating profit** totalled JPY 4,425 million (US$29.3 million) vs. a core operating loss of JPY 3,920 million (US$28.4 million) in the prior corresponding period.
- Cash and cash equivalents as at 30 September 2024 amounted to JPY 48,868 million (US$343.8 million) having decreased by JPY 197 million (decreased by US$4.2 million) from the beginning of the year.

**Convenience conversion to US$ at the following rates: FY 2024: 1US$ =151.14 JPY; FY 2023: 1US$ =138.09 JPY; 30 Sep 2024: 1US$ = 142.16 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).

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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 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.