

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

Tokyo, Japan and Cambridge, UK, 9 May 2024 – Nxera Pharma (“the Company” or “Nxera”; TSE: 4565) provides an update on operational activities and reports its consolidated results for the first quarter ended 31 March 2024. The full report can be found [here](#).

Chris Cargill, President and CEO of Nxera, commented: “We entered 2024 with a clear vision to capitalize on a number of strategic opportunities and build on the strong foundations we have created, positioning the business for the next stage of its journey to become a leading biopharmaceutical company in Japan. The last three months, defined by our bold actions, have been a testament to this.

“A key milestone this quarter has been the change of company name from Sosei Heptares to Nxera Pharma and the unveiling of a bold new brand and identity that captures our ambition to be pioneers of the next era of biopharmaceuticals and medicine. The decision to make this change was driven by the significant growth and development of the business, which has been accelerated through several key strategic acquisitions in recent years, and progress made advancing our extensive pipeline both in-house and with our partners.

“I extend my gratitude to our brilliant team in Japan, the UK, South Korea and Switzerland whose dedication and expertise has enabled these significant achievements and will empower our future success.”

Operational Highlights for Q1 2024

Corporate highlights

- Change of company name to Nxera Pharma
 - Approved on 27 March at the Company’s 34th Annual Shareholders’ Meeting and came into effect on 1 April 2024
- Appointment of Chief Operating Officer, Toshihiro Maeda
 - Mr Maeda, an experienced pharmaceutical executive, is leading the post-acquisition integration of the Nxera Pharma Japan (“NPJ”) and Nxera Pharma Korea (“NPK”) businesses into Nxera and will be responsible for all technical operations

Progress with in-house programs

- First subject dosed in a Phase 1 trial with NXE0033744, a novel, potent, selective and gut-restricted EP4 receptor agonist discovered by Nxera in development for the treatment of Inflammatory Bowel Disease (IBD)
- Regained full ownership from GSK of NXE0027477, a clinic-ready, highly selective, first-in-class, oral GPR35 agonist in development as a potential new treatment for IBD
 - Nxera expects to determine the optimal strategy for further clinical development of the program, which could include in-house development and/or re-partnering

Progress with partnered programs

- Entered a global collaboration and exclusive option-to-license agreement with Boehringer Ingelheim to develop first-in-class treatments targeting all symptoms of schizophrenia
 - Single-target agreement focused on development of novel, small molecule agonists of GPR52 discovered by Nxera with the potential to simultaneously address positive, negative and cognitive symptoms of schizophrenia
 - Nxera received EUR 25 million upfront from Boehringer Ingelheim and is eligible for an option exercise payment of EUR 60 million and further milestone payments totalling up to EUR 670 million plus tiered royalties
- US\$2.5 million milestone payment received from Formosa Pharmaceuticals for US approval of APP13007 (originally designed and developed at Activus Pharma, formerly a wholly owned subsidiary of the Company), for the treatment of post-operative inflammation and pain following ocular surgery

Post-period events

- 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
- 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
- Joined the World Orphan Drug Alliance (“WODA”) to represent WODA in Japan and South Korea
 - Through the Alliance 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

Financial Highlights for the Three-month Period ended 31 March 2024

- Revenue totalled JPY 4,611 million (US\$31.1 million*), an increase of JPY 3,668 million (US\$23.9 million) vs. the prior corresponding period. The increase is primarily due to the inclusion of NPJ in the scope of consolidation from July 2023, which resulted in the addition of PIVLAZ® sales.
- R&D expenses totalled JPY 3,163 million (US\$21.3 million), an increase of JPY 1,206 million (US\$6.5 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 414 million (US\$2.8 million) has been included for R&D expenses relating to NPJ/NPK.
- G&A expenses totalled JPY 3,650 million (US\$24.6 million), an increase of JPY 2,541 million (US\$16.2 million) vs. the prior corresponding period. This increase was primarily due to incremental spend on personnel and professional fees to strengthen our organizational capabilities, as well as the cost of integrating our IT systems and unifying the Group under the Nxera Pharma brand. JPY 2,049 million (US\$13.8 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 3,076 million (US\$20.7 million) vs. an operating loss of JPY 1,964 million (US\$14.8 million) in the prior corresponding period. This increase reflects the combined effect of all movements explained above.
- Loss before income tax totalled JPY 2,796 million (US\$18.8 million) vs. a loss before income tax of JPY 1,863 million (US\$14.1 million) in the prior corresponding period. This increase reflects the combined effect of all movements explained above.
- Net loss for the three-month period ended 31 March 2024 totalled JPY 3,281 million (US\$22.1 million) vs. a net loss of JPY 1,402 million (US\$10.6 million) in the prior corresponding period. This increase reflects the combined effect of all movements explained above.
- Core operating loss** totalled JPY 931 million (US\$6.3 million) vs. a core operating loss of JPY 1,465 million (US\$11.1 million) in the prior corresponding period.
- Cash and cash equivalents as at 31 March 2024 amounted to JPY 46,515 million (US\$307.3 million) having decreased by JPY 2,550 million (US\$40.6 million) from the beginning of the year.

**Convenience conversion to US\$ at the following rates: FY 2024: 1US\$ =148.40 JPY; FY 2023: 1US\$ =132.32 JPY; 31 Mar 2024: 1US\$ = 151.35 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.*

–END–

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

LinkedIn: [@NxeraPharma](https://www.linkedin.com/company/nxera-pharma) | X: [@NxeraPharma](https://twitter.com/NxeraPharma) | YouTube: [@NxeraPharma](https://www.youtube.com/channel/UC...)

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.