Nxera Pharma Operational Highlights and Consolidated Results for the Third Quarter 2026

Tokyo, Japan and Cambridge, UK, 30 October 2026 – Nxera Pharma ("the Company" or "Nxera"; TSE: 4565) provides an update on operational activities and reports its consolidated results for the third quarter ended 30 September 2026. The full report can be found here.

Chris Cargill, President and CEO of Nxera, commented: "During the third quarter of FY2026, we continued to build on the progress made in the first half, focusing on growing our business and enhancing the value of our pipeline. In Japan, we remained focused on maximizing the value of PIVLAZ® and QUVIVIQ®.

We also made important progress across our partnered programs. Under our collaboration with Neurocrine Biosciences Inc. ("Neurocrine"), we achieved a US$10 million milestone following progress in the development of NBI-1117567, an M1 receptor agonist for cognitive impairment associated with Alzheimer's disease. A further US$8.6 million milestone was achieved following late-stage development progress in the orexin receptor 2 (OX2R) agonist program originating from our collaboration with Centessa Pharmaceuticals Limited ("Centessa"), which was acquired by Eli Lilly and Company ("Lilly"). These achievements demonstrate how assets originating from our drug discovery technology are generating revenue as they advance through development with our partners.

Since the end of the third quarter, we have continued to advance our business in Japan and the broader Asia-Pacific region. In October, we submitted a Marketing Authorization Application in South Korea for vamorolone for the treatment of Duchenne muscular dystrophy (DMD), marking an important step towards bringing a new treatment option to patients in that territory.

We also entered into an exclusive license, supply and commercialization agreement with Synmosa Biopharma Corporation ("Synmosa") for QUVIVIQ® across eight Asia-Pacific markets, establishing a foundation to bring this medicine to more patients. In addition, we exercised our option to license the Fabry disease candidate lucerastat from Idorsia Pharmaceuticals Ltd. ("Idorsia"), strengthening our late-stage rare disease pipeline in Japan and the broader Asia-Pacific region.

These achievements demonstrate that our drug discovery, development and partnering strategy is delivering tangible results and strengthening the foundation for future growth. We remain focused on growing our commercial business in Japan and the broader Asia-Pacific region, advancing our partnered programs and maximizing the value of our proprietary pipeline, as we continue to drive sustained growth and value creation for patients and shareholders."

Operational Highlights for the Nine Months Ended 30 September 2026

Progress in Japan and APAC Business

- Licensing agreement signed with Santhera Pharmaceuticals for the development, manufacturing and commercialization of vamorolone (commercialized internationally as AGAMREE®) for the treatment of Duchenne Muscular Dystrophy (DMD) in Japan, South Korea, Australia and New Zealand.

- The Ministry of Food and Drug Safety (MFDS) of South Korea granted Orphan Drug Designation (ODD) and Global Innovative Products on Fast Track (GIFT) designation to vamorolone for the treatment of DMD to support faster patient access.
- Nxera is on track to submit a planned Marketing Authorization Application (MAA) for vamorolone in South Korea during 2026.

- Positive topline results announced from a randomized, double-blind, placebo-controlled Phase 3 trial in South Korea evaluating daridorexant, a dual orexin receptor antagonist, in adult and elderly patients diagnosed with insomnia disorder.
  - On 4 March 2026, an MAA was submitted to MFDS in South Korea for daridorexant for this patient population.
- Marketing approval received by Nxera's commercial licensing partner Holling Bio-Pharma Corp. ("Holling"), the largest pharmaceutical distribution and sales company in Taiwan, from the Taiwan Food and Drug Administration (TFDA) for QUVIVIQ® (daridorexant; Taiwan brand name: 科唯可®) 25 mg and 50 mg for the treatment of insomnia in adult patients.
  - Nxera will be responsible for the supply of drug product, while Holling will be responsible for distribution and sales.
  - Nxera is entitled to receive initial sales-related milestones, tiered royalties on net sales, and revenue from product supply.
  - QUVIVIQ® is expected to be launched in Taiwan during 2026.

Progress since 1 October 2026

- Nxera signed an exclusive license, supply and commercialization agreement with Taiwan-headquartered Synmosa Biopharma Corporation for QUVIVIQ®, a treatment for insomnia, in Singapore, Thailand, Indonesia, Malaysia, the Philippines, Vietnam, Australia and New Zealand. Under the agreement, Nxera will receive an upfront payment and is eligible to receive regulatory approval milestone payments in the licensed territories, royalties on sales and revenue from product supply.
- Nxera announced the submission of a Marketing Authorization Application (MAA) to South Korea's MFDS for vamorolone for the treatment of DMD. The Company is targeting regulatory approval in South Korea in 2027 and commercial launch in 2028.
- Nxera announced that it has exercised its option to in-license lucerastat, a treatment candidate for Fabry disease, and entered into a co-development and commercialization agreement with Idorsia. Under the agreement, Nxera holds exclusive rights to develop and commercialize lucerastat in Japan, South Korea, Taiwan and selected other Asia-Pacific markets (excluding China). Nxera will pay Idorsia an upfront payment of CHF 7 million and contribute to the global Phase 3 development program, which is expected to support a regulatory filing as early as 2029.

Progress with partnered programs

- Neurocrine Biosciences ("Neurocrine") initiated and dosed the first patients in a Phase 2 clinical study of NBI-1117570 ("NBI-'570") – an oral dual muscarinic M1/M4 receptor agonist – in adults with schizophrenia. As a result, Nxera received milestone payments of US$22.5 million from Neurocrine, which were recognised as revenue in Q1 FY2026. Nxera announced that the U.S. Food and Drug Administration (FDA) had accepted the Investigational New Drug (IND) application for a Phase 2 study of NBI-1117567, a muscarinic M1-preferring (M1/M4) selective agonist, for cognitive impairment associated with Alzheimer's disease. As a result, Nxera received a US$10 million milestone payment from Neurocrine, which was recognized in full as revenue in Q3 FY2026. The status of the other programs in the partnered muscarinic receptor agonist portfolio is as follows:

- Direclidine/NBI-1117568 (an oral, muscarinic M4-selective agonist): Phase 3 studies in schizophrenia ongoing, with readouts expected in 2027 and 2028; a Phase 2 study in bipolar mania also ongoing.
- NBI-1117569 (a dual M1/M4 agonist): results from a Phase 1 study targeting Alzheimer's psychosis expected to be announced in 2027.

- Centessa Pharmaceuticals Limited (“Centessa”) entered a definitive agreement to be acquired by Eli Lilly and Company ("Lilly") on 31 March 2026 and the transaction was successfully completed on 24 June 2026.
  - The acquisition centers on Centessa's novel orexin receptor 2 (OX2R) agonist series, cleminorexton/ORX750, ORX142 and ORX489, which was jointly created by Centessa and Nxera.
  - Nxera remains entitled to receive certain success-based milestone payments and royalties for all these OX2R agonists, and the original contractual terms are unaffected by this transaction.
  - Under the collaboration with Centessa, an early-stage development milestone was achieved for ORX142, the second novel orexin receptor 2 (OX2R) agonist, resulting in a payment of US$3.6 million. Two early-stage development milestones were also achieved for ORX489, an OX2R agonist being developed for neuropsychiatric disorders, resulting in further payments of US$4.8 million. A late-stage development milestone was achieved for the OX2R agonist program, resulting in a payment of US$8.6 million to Nxera.
- Achievement of a second development milestone under the multi-target collaboration and license agreement with Lilly targeting diabetes and metabolic diseases.
  - As a result, Nxera has received an undisclosed milestone amount, which was recognized as revenue in Q1 2026.
- Achievement of a third and fourth important research milestone under the multi-target discovery collaboration with AbbVie focused on neurological diseases, resulting in US$20 million in milestone payments to Nxera. The majority of these payments will be recognized as revenue in 2026, with the remainder to be recognized in 2027 and beyond.
- License agreement signed with a newly established company ("NewCo") co-founded by Nxera and leading healthcare and life sciences-focused investment firms regarding a GPCR-targeted program discovered and developed by Nxera.
  - Nxera acquired an equity stake in NewCo and is entitled to receive up to US$275 million in milestone payments based on development and commercialization progress, as well as tiered royalties on sales.
  - Nxera retains rights to develop and commercialize any assets generated by the program in Japan and certain Asia-Pacific territories.
  - Nxera also participated in NewCo’s Series A financing.

Financial Highlights for the Nine-month Period ended 30 September 2026

- Revenue totalled JPY 27,742 million (US$175.0 million*), an increase of JPY 5,894 million (US$27.6 million) vs. the prior corresponding period. This increase was primarily due to the achievement of ten R&D milestones during the nine months ended 30 September 2026, compared with six in the prior corresponding period. In addition, product sales were higher in the first nine months of 2026.
- R&D expenses totalled JPY 8,963 million (US$56.5 million), a decrease of JPY 2,237 million (US$19.0 million) vs. the prior corresponding period. This decrease was primarily due to the maturation of several clinical programs, together with the adoption of a more streamlined R&D focus.

- SG&A expenses totalled JPY 8,333 million (US$52.6 million), a decrease of JPY 1,023 million (US$10.6 million) vs. the prior corresponding period. This decrease was primarily due to targeted cost reduction initiatives.
- Operating profit totalled JPY 3,175 million (US$20.0 million) vs. an operating loss of JPY 5,907 million (US$39.9 million) in the prior corresponding period.
- Profit before income tax totalled JPY 2,565 million (US$16.2 million) vs. a loss before income tax of JPY 6,838 million (US$46.1 million) in the prior corresponding period.
- Net profit totalled JPY 2,328 million (US$14.7 million) vs. a net loss of JPY 4,809 million (US$32.5 million) in the prior corresponding period.
- Core operating profit** totalled JPY 9,818 million (US$61.9 million) vs. a core operating loss of JPY 986 million (US$6.6 million) in the prior corresponding period.
- Cash and cash equivalents as of 30 September 2026 amounted to JPY 16,613 million (US$105.6 million), having decreased by JPY 3,752 million (US$24.5 million) from the prior financial year end primarily due to investing activities.

**Convenience conversion to US$ at the following rates: FY 2026: 1US$ =158.52 JPY; FY 2025: 1US$ =148.18 JPY; 30 Sep 2026: 1US$ = 157.29 JPY; 31 Dec 2025: 1US$ = 156.47 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 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. The Company has built an agile, new-generation commercial business in Japan to develop and commercialize innovative medicines, including several launched products, to address this high-value, large and growing market and those in the broader APAC region. In addition, the Company is advancing an extensive pipeline internally and in partnership with leading pharma and biotech companies powered by its unique NxWave™ GPCR structure-based drug discovery platform. Nxera Pharma operates 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 | X: @NxeraPharma | YouTube: @NxeraPharma

Enquiries:

Nxera – Media and Investor Relations
Shinya Tsuzuki, VP, Head of Investor Relations
+81 (0)3 5962 5718 | +44 (0)1223 949390 |IR@Nxera.life

MEDiSTRAVA (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.