NON-CONFIDENTIAL

Nxera Pharma

# FY2024 Financial Results

## 12-month period ended December 31, 2024

14 February 2025 | Nxera Pharma Co., Ltd. (TSE: 4565)

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# Agenda

01 Financial Results

02 Operational Highlights

03 Japan /APAC Commercial Business

04 R&D Progress

05 FY2025 Objectives and beyond

06 Appendix

# Financial Results

Hironoshin Nomura, CFO

01

# Financial summary for FY2024

Revenue grew significantly due to M&A and partner milestones. Most non-recurring core costs ceased in 2024.

Revenue

**Revenue of JPY28,835m (+126%** | JPY12,766m in the prior year)

- PIVLAZ® sales grew significantly from JPY6.1bn to JPY12.7bn due to market penetration and full-year sales contribution (vs. 5 months in FY2023)
- Milestones increased from JPY2.3bn to JPY11.2bn due to the progress of partnered programs

Profit

**Core Operating Profit of JPY3,606m** (Core Operating Loss of **JPY3,076** in the prior year)

- R&D and SG&A expenses were lower than the cost estimates at the beginning of the year as the integration progressed well
- Operating Loss of JPY5,423m (Operating Loss of JPY9,526m in the prior year)
  - ➢ Non-core costs of JPY9,029m with additional CoS charge and non-recurring integration costs
  - ➢ Most of non-recurring integration costs and additional CoS charge ceased in FY2024

Cash

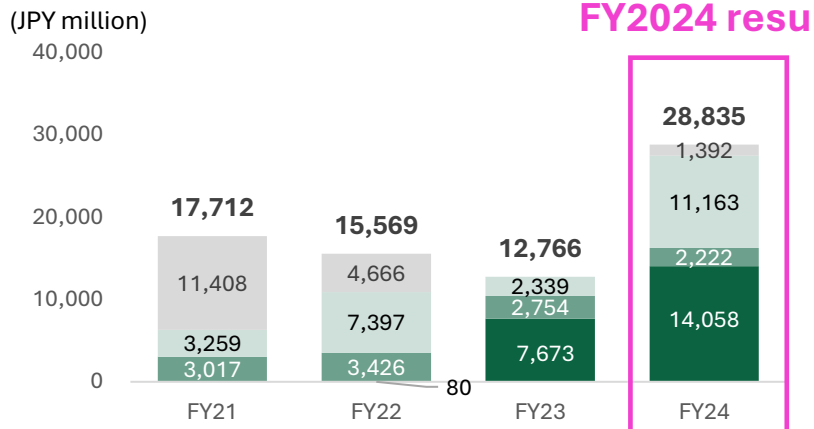
**Cash/Cash equivalents/Fix deposit: JPY36.2bn** (JPY49.0bn in the prior year)

- Purchased QUVIVIQ™ API (equivalent to more than one year of supply) to ensure the stable supply of QUVIVIQ™ in advance

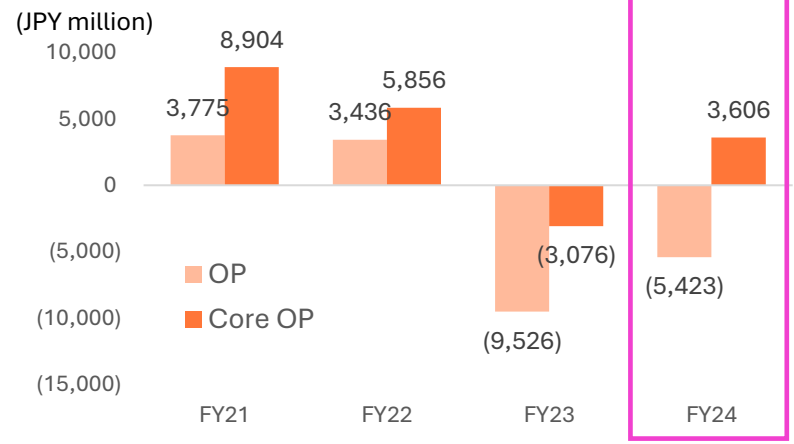
# Key financial indicators

## NPJ/NPK product sales and cost base fully included in FY2024. Milestones increased due to progress of partnered programs

**Revenue**




**Operating Profit / Loss**




**FY2024 result**

| | Major factors |
|---|---|
| Upfront[1] | ■ New option-to-license deal signed with Boehringer (March). |
| Milestone[2] | ■ USD15m M4 development milestone from Neurocrine (April).<br>■ USD10m milestone from AbbVie (June).<br>■ USD35m M4 Ph2 success milestone from Neurocrine (Sept). |
| Royalty / Other | ■ Royalties from Respiratory Portfolio with Novartis decreased. |
| Product Sales | ■ Increase in PIVLAZ® sales and full inclusion in 2024. |
| R&D | ■ Increased investment in R&D activities for clinical trials.<br>■ Inclusion of NPJ/NPK related R&D costs. |
| Cost of Sales | ■ Inclusion of PIVLAZ® product supply costs.<br>■ Additional non-cash CoS charge relating to PIVLAZ® inventory. |
| G&A | ■ Inclusion of NPJ/NPK related G&A costs.<br>■ Integration costs (incl. company name change).<br>■ Amortization of intangible assets (PIVLAZ®). |

[1] Upfront fee revenue recognised at deal inception
[2] Milestone revenue recognised at milestone event + deferred revenue releases

# Breakdown of 2024 results

## Impact of Non-cash/Non-recurring costs was more significant in 2024 due to the inclusion of the Idorsia businesses

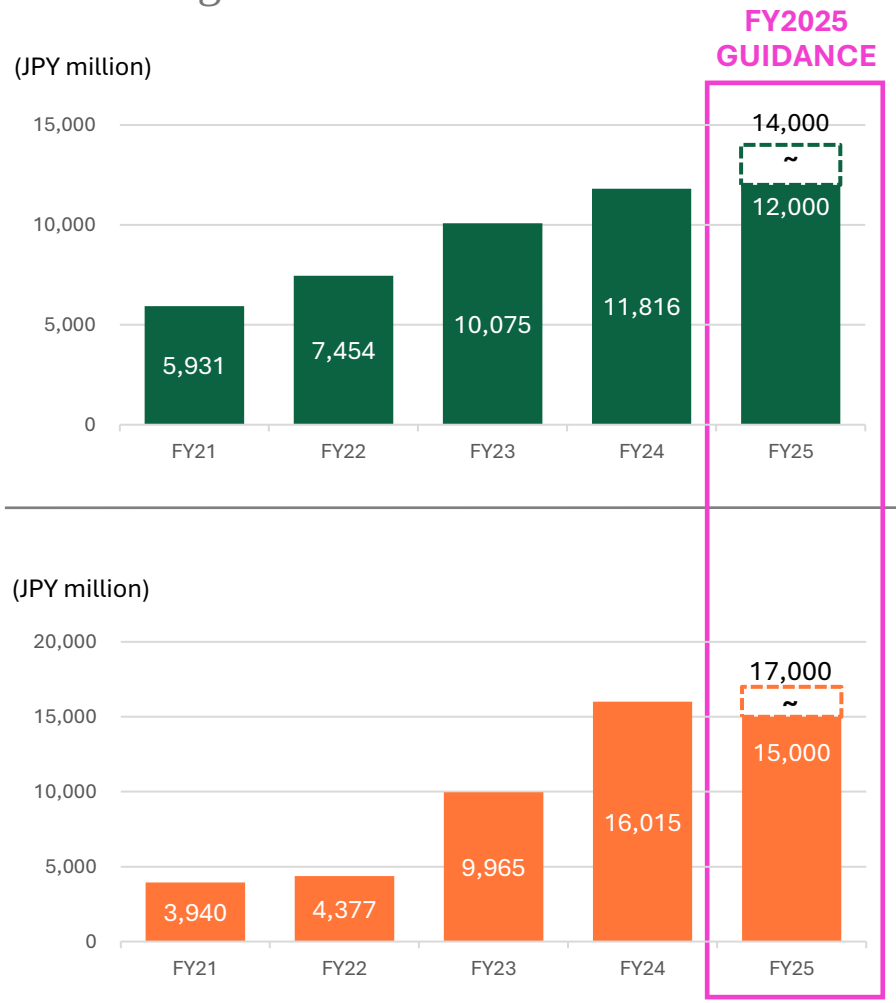
| (JPY million) | NPC / NPU*1 | + | NPJ / NPK*2 | = | Consolidated P&L (Core) | + | Non-cash costs | + | Non-recurring Costs | = | Consolidated P&L (IFRS) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue | 14,847 | | 13,988 | | 28,835 | | | | | | 28,835 |
| Cost of Sales + SG&A | (7,015) | | (8,963) | | (15,978) | | A (2,401) PIVLAZ® inventory adjustment<br>B (1,362) Amortization - Product IP | | C (1,160) Integration<br>D (2,730) Other | | (23,630) |
| R&D | (9,258) | | (1,242) | | (10,500) | | D (1,316) | | | | (11,816) |
| Other income | 1,272 | | (23) | | 1,249 | | D (60) | | | | 1,189 |
| **OP/Core OP** | **(154)** | | **3,760** | | **Core OP 3,606** | | Total : 9,029 | | | | **OP (5,423)** |

| | |
|---|---|
| M&A related costs | A Additional CoS charge for PIVLAZ® stock which completed by 3Q 2024.<br>B Amortization of intangible assets (currently relates to PIVLAZ®). Annual charge to increase to c. JPY 1,800m per year from 2025.<br>C Integration costs including IT system integration and Corporate rebranding. Will significantly decrease in 2025. |
| Other | D Amortization of other intangible assets (e.g. IP), depreciation (e.g. laboratory equipment), share-based payments and other restructuring costs. |

*1 = Nxera Pharma Co. Ltd. (formerly Sosei Group Corporation) + Nxera Pharma UK Ltd (formerly Heptares Therapeutics Ltd.) + Sosei K.K
*2 = Nxera Pharma Japan (formerly Idorsia Pharmaceuticals Japan) + Nxera Pharma Korea (formerly Idorsia Pharmaceuticals Korea)

# Full year cost guidance for FY2025

Slight increase in R&D expenses with progression of programs into later stages of development and in-licensing of one or more late-stage candidates. Lower to flat SG&A expenses through streamlining costs




## R&D expenses (IFRS basis)

**JPY12,000 to JPY14,000m**

**Key points in FY2025**

- Incremental investment in platform technology.
- In-house programs (EP4 ant., EP4 ago., GPR52 ago.) moving into Ph1b - Ph2.
- Clinical development of one or more in-licensed late-stage assets in Japan.

## S&M + G&A expenses (IFRS basis)

**JPY15,000 to JPY17,000m**

**Key points in FY2025**

- Investment in technology to increase efficiency and deliver future growth.
- Increase in amortization as QUVIVIQ™ has launched.
- Lower or flat SG&A expenses vs. FY2024 through cost savings.

# Operational Highlights

Chris Cargill, President and CEO

02

# Recap of FY2024 Priority Objectives

| | | |
|---|---|---|
| 01 | JPY 15-16 billion NHI sales for PIVLAZ® | ✓ JPY 15.2Bn |
| 02 | JNDA approval for daridorexant in Japan | ✓ Sep. 2024 |
| 03 | Acquire/in-license at least one late-stage medicine for Japan/APAC (ex-China) | *Ongoing discussions* |
| 04 | Execute at least one new major partnership, and initiate at least one new in-house Ph.1 study | ✓ GPR52 ag. Boehringer Ingelheim<br>✓ EP4 ag. (In-house)<br>✓ クービビック® SHIONOGI |
| 05 | PMI investment in new brand concept, plus systems and applications for efficiency and scalability | ✓ Successfully executed |

# Advancing as a global biopharma with strong foundations

## CORPORATE MILESTONES

- ✓ Rebranding from Sosei Heptares to Nxera Pharma
- ✓ Senior team strengthened with appointments of new COO and CMO
- ✓ PMI investment in new brand concept and IT infrastructure

## UK R&D

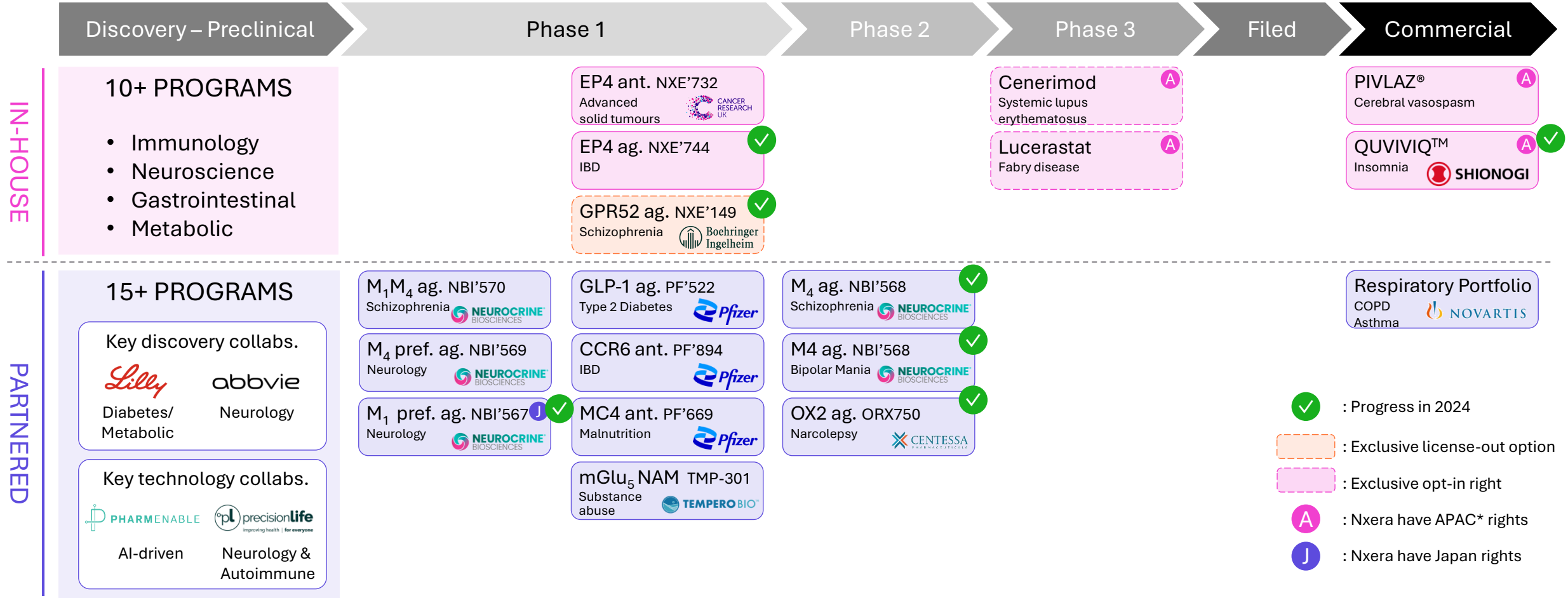
- ✓ New option-to-license deal with Boehringer Ingelheim (GPR52 agonists)
- ✓ Successful Ph2 study of NBI-568 (M4 agonist)
- ✓ ORX750 entered Ph2 study (OX2 agonist)
- ✓ NBI-567 entered Ph1 study (M1 preferring agonist)
- ✓ NXE'744 entered Ph1 study (EP4 agonist)

## JAPAN/APAC BUSINESS

- ✓ PIVLAZ® established strong position in Japan
- ✓ Japan NDA approval and launch of QUVIVIQ™
- ✓ Commercial partnership with Shionogi for QUIVIVQ™
- ✓ Daridorexant entered Ph3 study in South Korea

**Accelerating science, expanding capabilities and delivering impact**

# Broad and balanced pipeline with two recently launched products driving top-line growth




**Clinical pipeline quickly shifting towards late-stage clinical development**

Note: Pref. ag. : Preferring agonist. *APAC (ex-China) territory includes Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

# Delivering science with commercial potential

## Nxera's Commercialized Products

**1** Neurological disorders – diseases of ageing

**PIVLAZ®**

エンドセリン受容体拮抗薬 薬価基準収載 ピヴラッツ®点滴静注液 150mg

– prevention of cerebral vasospasm in patients with Aneurysmal Subarachnoid Hemorrhage (aSAH)

**2** Neurological disorders – quality of life diseases

**QUVIVIQ™**

不眠症治療薬 / オレキシン受容体拮抗薬 薬価基準未収載 クービビック®錠 25mg 50mg

– treatment of adult patients with insomnia

**JPY30–35bn** product sales by 2030
(plus, multiple other programs in discovery/development)

## Partnered Products (Discovered by Nxera/with NxWave™ tech)

**3** Neurological disorders – psychiatric / cognition

NEUROCRINE® BIOSCIENCES – ***Muscarinic agonists***

**4** Neurological disorders – QOL diseases - sleep

CENTESSA PHARMACEUTICALS – ***Orexin 2 agonists***

**5** Metabolic diseases – QOL diseases - T2D / obesity

Pfizer – ***GLP-1 agonist***

**Up to JPY250bn** royalty revenues at peak
(plus, multiple other programs in discovery/development)

# Japan/APAC Commercial Business

President of Nxera Pharma Japan and Chief Medical Officer

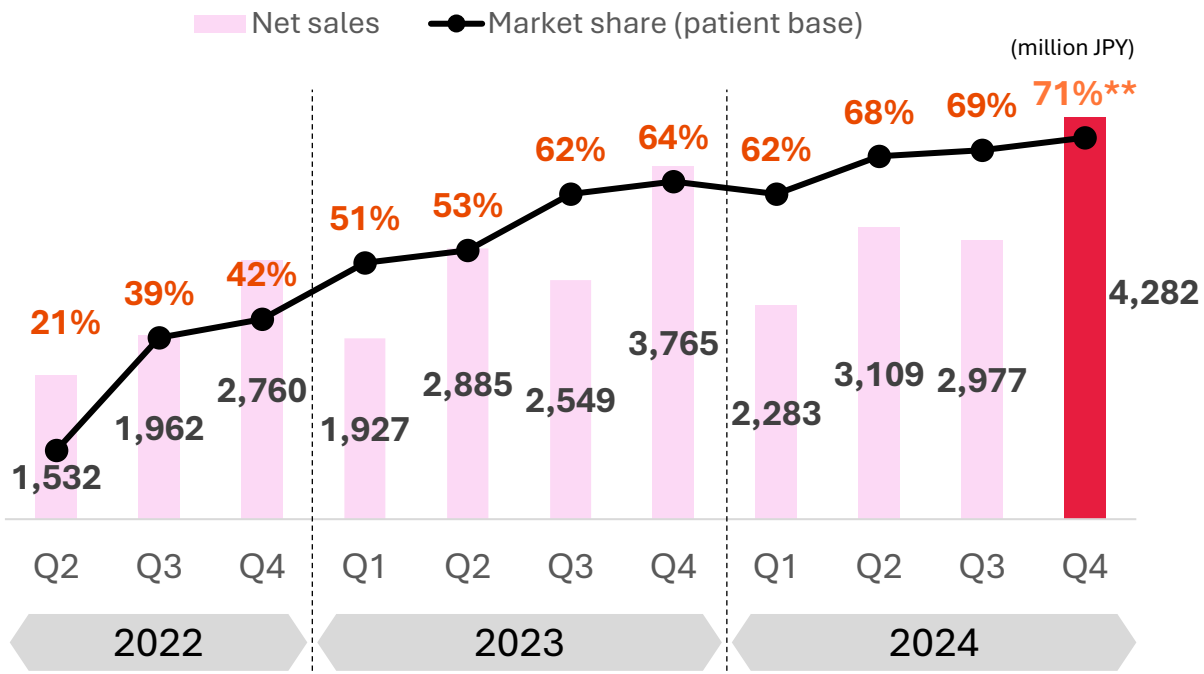
03

# 1 PIVLAZ® (clazosentan, an endothelin A antagonist)

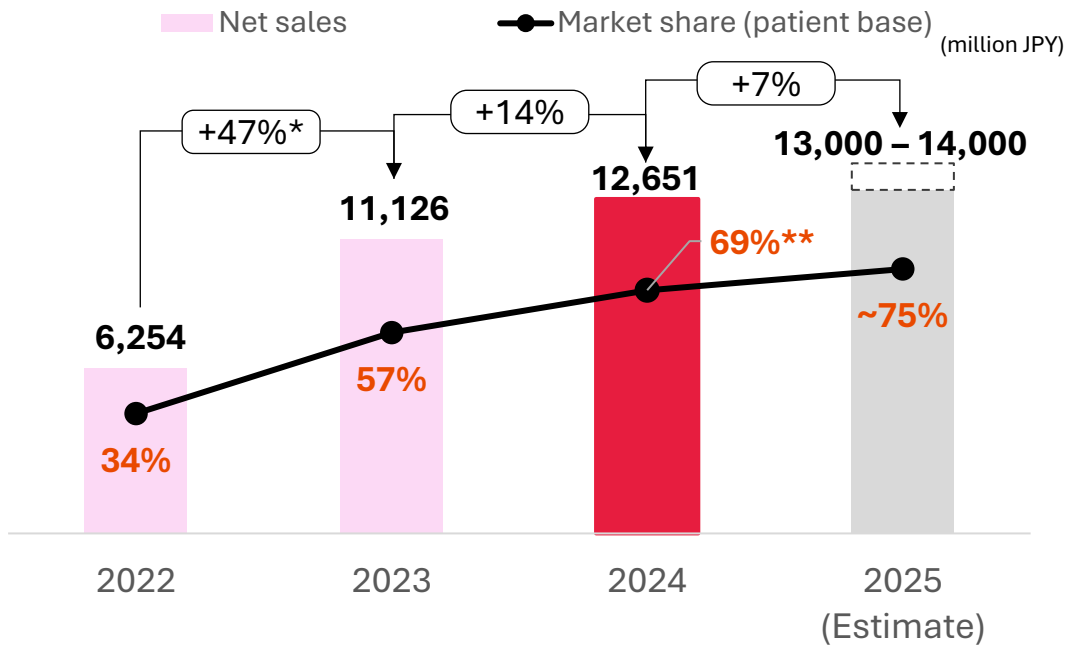
Our first commercially available product for the prevention of cerebral vasospasm in patients with Aneurysmal Subarachnoid Haemorrhage (aSAH)

エンドセリン受容体拮抗薬 薬価基準収載
ピヴラッツ® 点滴静注液 150mg

## Quarterly PIVLAZ® Net Sales




## Annual PIVLAZ® sales and its growth




PIVLAZ® has rapidly built awareness and is becoming the standard of care with neurosurgeons

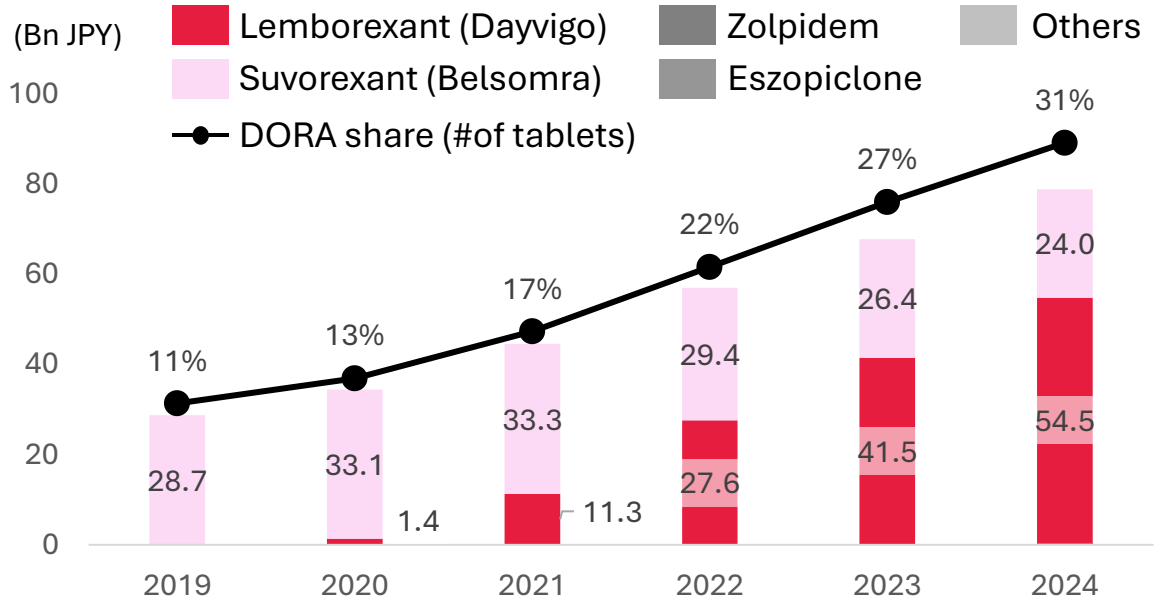
Source: MDV DPC hospital data
*: Comparison of 2-4Q of 2022 and 2023, **: Estimation

# 2 QUVIVIQ™ (daridorexant, dual orexin antagonist "DORA")

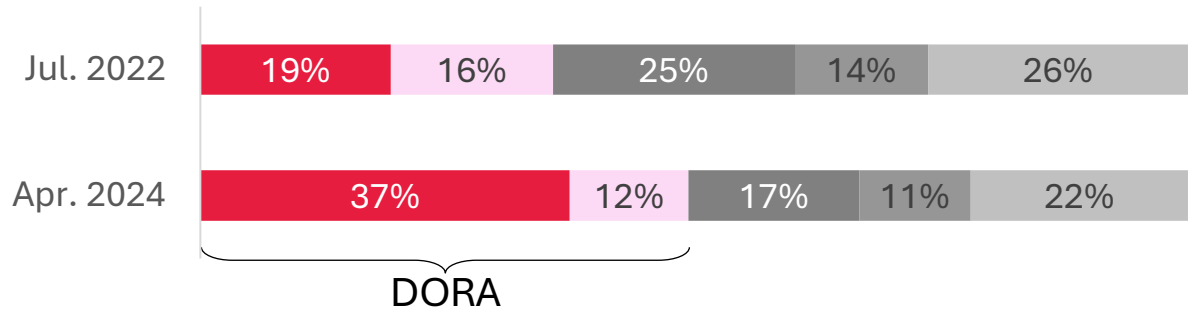
## DORA is rapidly establishing its position in the treatment paradigm for insomnia

不眠症治療薬 / オレキシン受容体拮抗薬 クービビック®錠 25mg 50mg 薬価基準未収載

**Sales and market share** (NHI-base)




**Prescription share** (Most frequently prescribed sleeping pills)




- ✓ DORAs are rapidly penetrating the insomnia treatment market in Japan, where traditional anti-anxiety and z-class drugs are not preferred by physicians
- ✓ Japan is one of the largest DORA markets globally – estimated at up to US$1bn
- ✓ Together with partner Shionogi, we aim to provide a best-in-class product

Source: Nikkei Medical (2022/7/23, 2024/4/13), Encise

# 2 QUVIVIQ™: APAC expansion

Making progress in developing the APAC market to maximize the product value

不眠症治療薬 / オレキシン受容体拮抗薬 クービビック®錠 25mg 50mg 薬価基準未収載

| | Partner | Market potential (# of insomnia patient) | Expected launch | Partnering structure |
|---|---|---|---|---|
| Japan | SHIONOGI | > 20 million | Launched | Distribution and sales |
| South Korea | Local company (undisclosed) | 6.5 - 11 million | 2027 | Development collaboration (Sales and marketing: TBD) |
| Other APAC countries | Under negotiation with potential partners | - | - | - |

# Full year product sales guidance

## Target 13.0 - 14.0 Bn JPY (PIVLAZ) as net sales, and 4.0 - 5.0 Bn JPY (QUVIVIQ) as royalty and supply

エンドセリン受容体拮抗薬 薬価基準収載
ピヴラッツ® 点滴静注液 150mg

不眠症治療薬 / オレキシン受容体拮抗薬 薬価基準未収載
クービビック® 錠 25mg 50mg

**Target sales in FY2025**

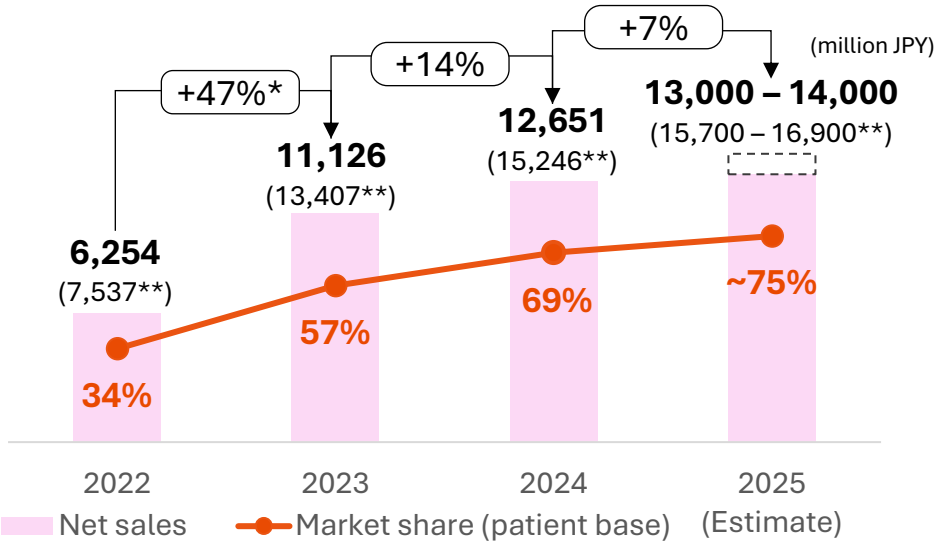
**13.0 – 14.0 Bn JPY**
(NHI Sales:15.7 – 16.9Bn JPY)

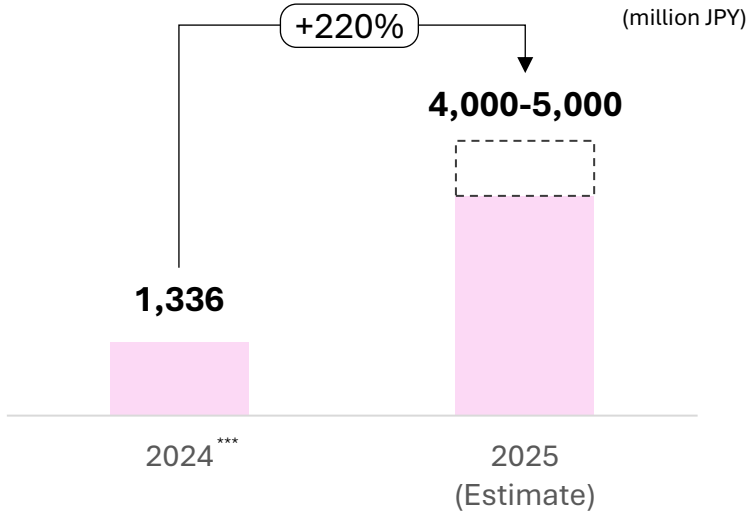
+7%

**4.0 – 5.0 Bn JPY**

+220%

**Sales trend**




Source: MDV DPC hospital data

*: Comparison of 2-4Q of 2022 and 2023, ** NHI sales, *** 2024 sales includes upfront, milestone, royalty and product supply while 2025 sales includes royalty and product supply

# R&D Progress

Dr. Matt Barnes, President of Nxera Pharma UK
and Head of UK R&D

04

To be presented today

# Key Events 2024

## Accelerating the development of life-changing medicines, by investing in science and technology

### PRE - DISCOVERY

precisionlife — improving health | for everyone

Expansion of R&D partnership into auto-immune disorders

PR LINK

May '24

abbvie

$10M milestone payment received from neurology collaboration utilising NxWave™ platform

PR LINK

Jun '24

Antiverse

Collaboration to design novel GPCR targeted antibody therapeutics using Generative AI

PR LINK

Nov '24

### DISCOVERY

Nxera

Two NME[1] programs transitioned into the Discovery

H1 '24

GSK

GPR35 agonist program reversion from GSK completed

PR LINK

H1 '24

### PHASE 1

Nxera

Phase 1 trial start evaluating NXE'744, a potent, selective, GI targeted, EP4 agonist for IBD

PR LINK

Mar '24

Boehringer Ingelheim

Collaboration with BI signed (€25M upfront and €60M option exercise) for FIC GPR52 agonists for schizophrenia

PR LINK

Mar '24

CENTESSA PHARMACEUTICALS

$4.6M milestone payment received for ORX750 (OX2R agonist) Phase 1 start in Narcolepsy

PR LINK

May '24

NEUROCRINE BIOSCIENCES

NBI-567, oral muscarinic M1 preferring agonist Phase 1 start with potential to treat symptoms of cognition in patients

PR LINK

May '24

### PHASE 2

NEUROCRINE BIOSCIENCES

$15M milestone triggered on successful completion of long-term preclinical toxicology of NBI-568, an oral selective muscarinic M4 agonist advancing through Phase 2

PR LINK

Apr '24

$35M milestone triggered upon successful completion of the Phase 2 trial in adults with schizophrenia

PR LINK

Sep '24

CENTESSA PHARMACEUTICALS

Centessa Pharmaceuticals initiated a Phase 2 trial of OX750 in Narcolepsy (NT1 & NT2) and idiopathic hypersomnia

PR LINK

Nov '24

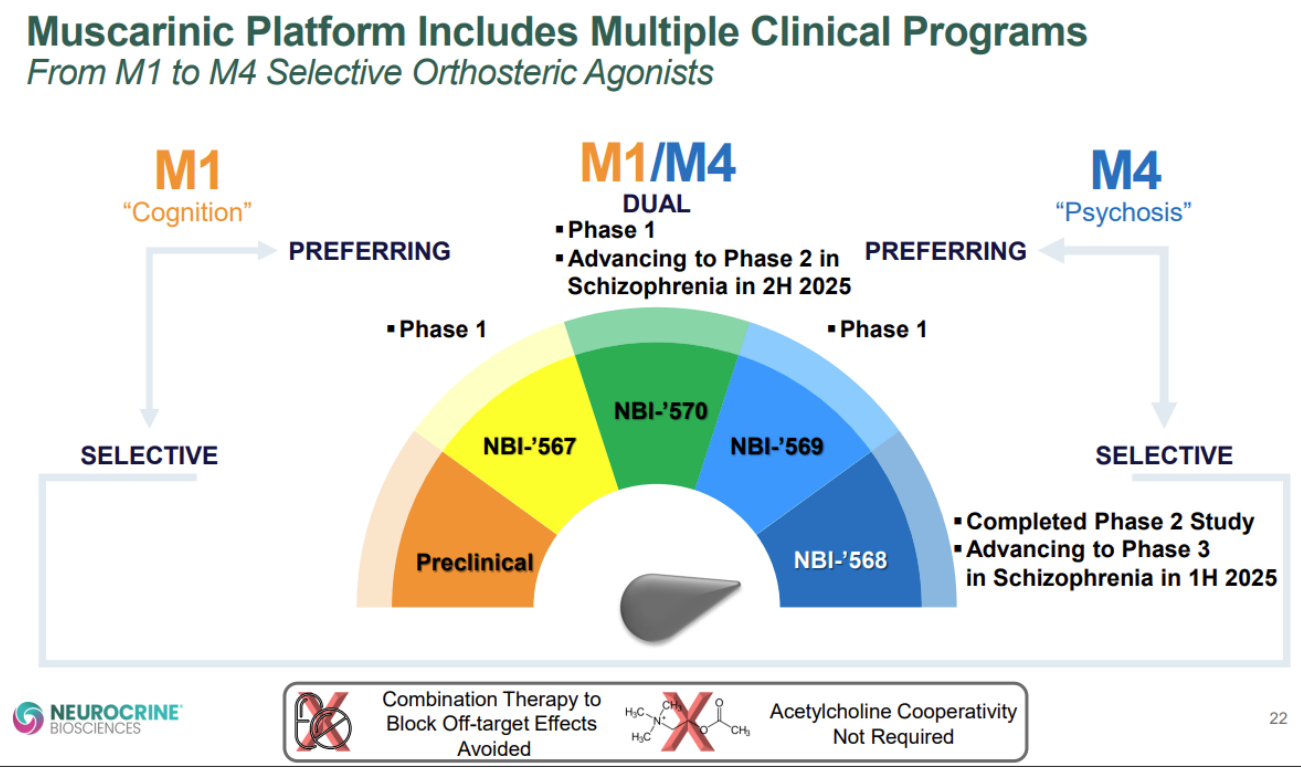
**World-leading NxWave™ SBDD platform continues to fuel innovation & clinical success**

[1] NME = New Molecular Entity



Nxera

# Neurocrine is advancing the world's most comprehensive portfolio of muscarinic orthosteric agonists – discovered by Nxera using NxWave™



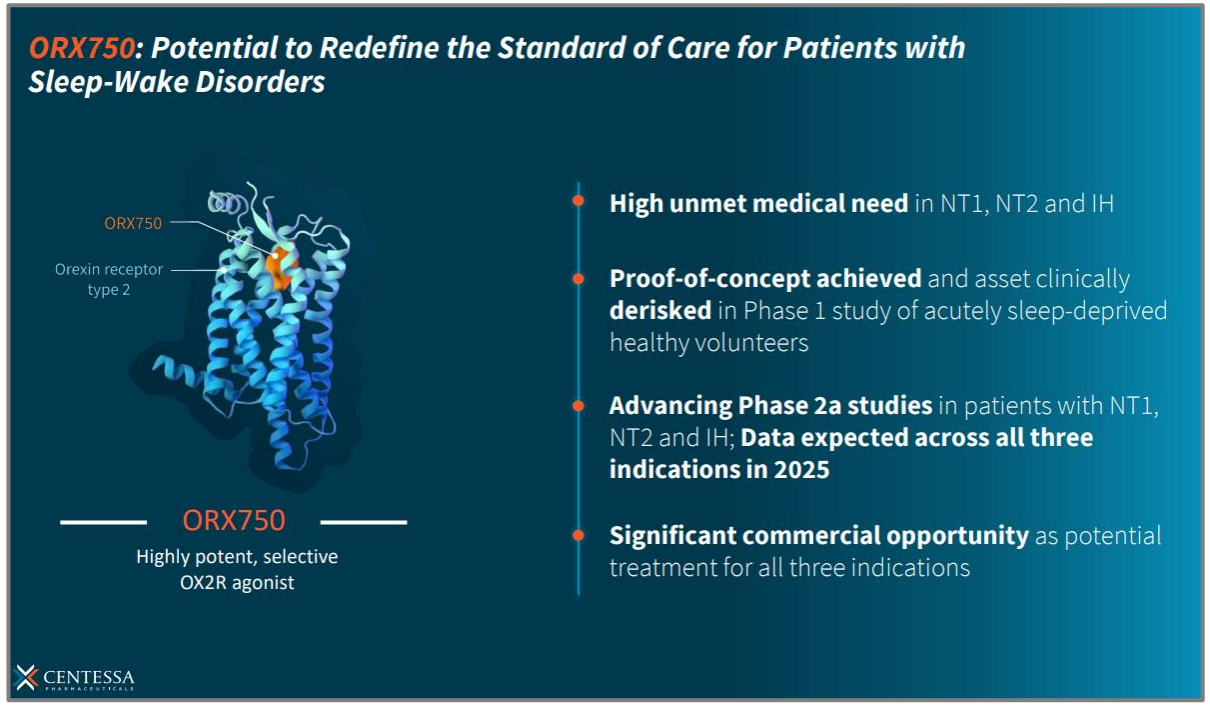

## Highlights

- NxWave™ platform enabled full suite of Structurally-enabled small molecule programs across key receptors
- Comprehensive approach to maximising the potential of muscarinic agonism
- **NBI-568**: Lead M4 selective orthosteric agonist, completed Phase 2 in 2024 and initiating Phase 3 registrational studies in Schizophrenia in 1H 2025 & Phase 2 in Bipolar Mania in 2H 2025
- **NBI-570:** dual M1 / M4 agonist anticipating the initiation of a Phase 2 study in Schizophrenia in 2H 2025
- **NBI-567:** M1 agonist Phase 1 is ongoing, initial data readout expected in 2025

From M1 to M4 selective orthosteric agonists targeting neurological and neuropsychiatric conditions

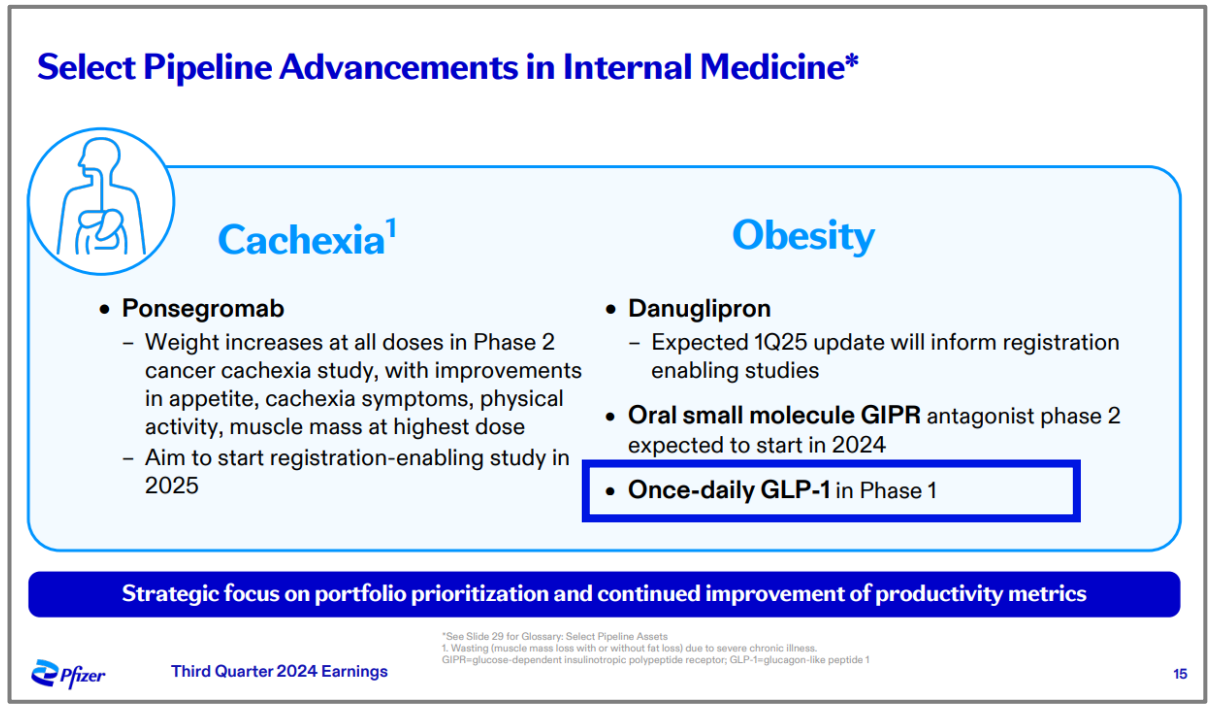
Source: Neurocrine Biosciences Q4 and Year-End 2024 Earnings Presentation

# Centessa advancing Orexin 2 agonists - ORX750 in Phase 2 as an improved treatment for Narcolepsy Type 1 and beyond – discovered using NxWave™




Significant commercial opportunity for best-in-class lead program ORX750 across NT1, NT2, and IH

# Pfizer advancing PF'522, once-daily, small molecule GLP-1 agonist in Phase 1 for T2D and obesity – discovered by Pfizer using NxWave™




Pfizer "all-in" on oral small molecules for metabolic disease. Huge need for convenient, cost effective, scalable products

Source: Centessa, Pfizer investor presentations

# Fuelling the Wave 1 and Wave 2 launches with novel programs in neurology and immunology

| | OPTION TO LICENSE WITH Boehringer Ingelheim / DISCOVERED BY Nxera | DISCOVERED BY Nxera | DISCOVERED BY Nxera |
|---|---|---|---|
| **Compound & Stage** | NXE-149 (Ph 1b) | NXE-732 (Ph 1) | NXE-744 (Ph 1) |
| **Target Indication** | Schizophrenia | Advanced solid tumors | IBD |
| **Global Patient Population** | **24 million** | **18 million** | **10 million** |
| **Mechanism** | Novel, selective GPR52 receptor agonism | Selective EP4 receptor antagonist in combo with PD-L1 | Novel, selective EP4 receptor agonist |
| **Novelty** | First-in-Class | Best-in-Class | First-in-Class |

Continuing to design convenient, cost effective, easy to manufacture, oral small molecule medicines with the potential to change the treatment paradigm for major diseases

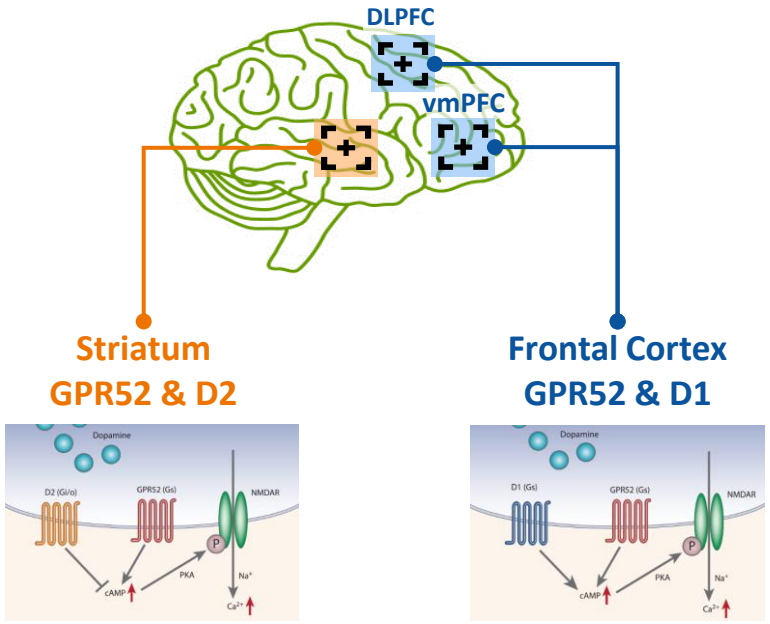
Source : World Health Organization

# GPR52 Agonist for Schizophrenia

## A Novel First-In-Class Mechanism to Treat Positive, Negative & Cognitive Domains of Schizophrenia

### Disease Rationale

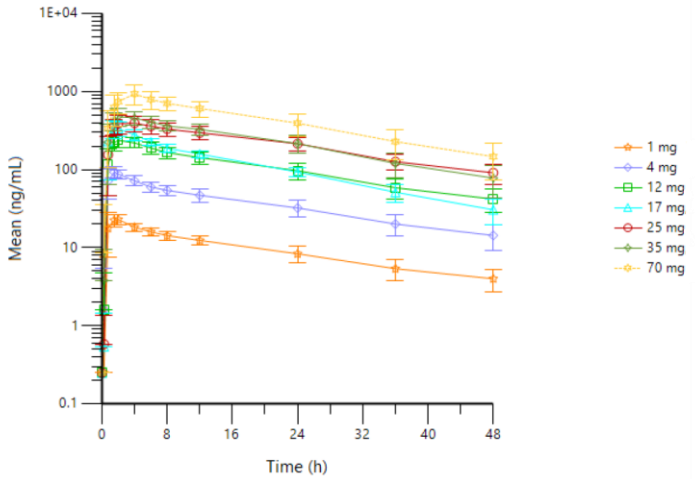
- GPR52 is expressed on D2 dopamine neurons in striatum where activation could lead to D2 antagonist-like effect to treat positive symptoms, e.g. hallucinations
- GPR52 also co-located with D1 dopamine receptor in prefrontal cortex where activation could lead to D1 agonist-like effect to improve cognition, e.g. attention




### Progress

- **Ph1a study completed**
  - Pharmacodynamic measures included
  - PK data is robust and in line with preclinical predictions
  - Support once daily dosing
- **Ph1b study initiated and will complete by 2H 2025**
  - Proof of Mechanism study
  - A study with a pharmacodynamic endpoint to confirm GPR52 activation in the brain

**SAD PK data**




GPR52 Ag study link: https://www.isrctn.com/ISRCTN17231793?q=&filters=&sort=&offset=58&totalResults=23608&page=6&pageSize=10

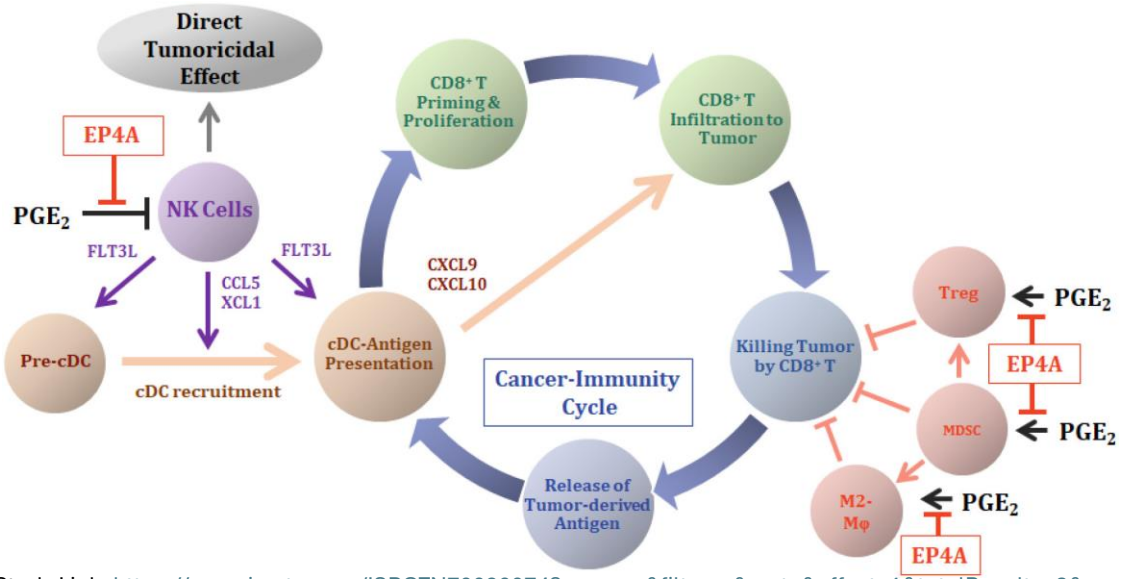
# EP4 Antagonism for Advanced Solid Tumours

## Alone or in Combination with Checkpoint Inhibitors (CPIs)

CANCER RESEARCH UK

### Disease Rationale

- Prostaglandin E2 (PGE2) is secreted by tumour and surrounding tissue and signals through EP4 to suppress the immune system
- EP4 antagonism is expected to restore immunosurveillance and enhance the effect of CPIs
- Less than 20% of eligible patients derive benefit from CPIs, meaning there is a great unmet need




### Progress

- **Ph1 study will complete Q1 2025**
  - Ph1 Part A completed (monotherapy escalation study)
  - Ph1 Part B will complete soon (combination escalation study)
- **Robust interim data to date in Ph1 study**
  - AEs have been generally mild (grade 1-2 ) and have resolved without dose interruption.
  - PK profile remains is in line with predictions and exhibits general dose proportionality across all dose levels tested.
  - Target engagement has been observed at all dose levels tested and additional pharmacodynamic analysis, including evaluation of paired biopsies for T cell infiltration, is underway.
- **Ph1 clinical data will be disclosed 2H 2025**
- **Ph2a start is expected Q2 2025**

Study Link: https://www.isrctn.com/ISRCTN70080074?q=nxera&filters=&sort=&offset=1&totalResults=2&page=1&pageSize=10



NXERA

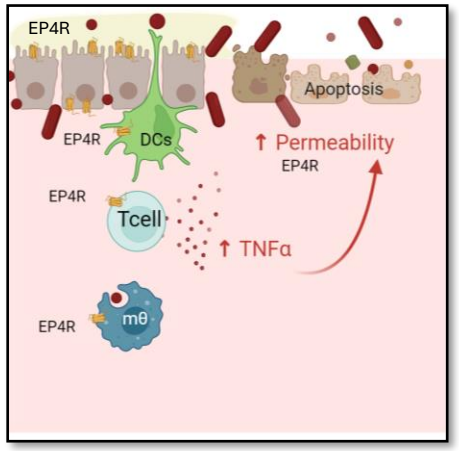
# EP4 Agonist for Inflammatory Bowel Disease (IBD)

## A First-In-Class GI-Targeted Agent to Promote Mucosal Healing in IBD

### Disease Rationale

- IBD is an immunological disorder in which current standard-of-care agents have treatment ”ceilings” of about 40% response rates.
- All approved IBD agents are immunomodulatory in nature and do not directly target disease-induced mucosal barrier defects.
- Through combined anti-inflammatory and barrier repair effects, EP4 agonists are expected to bring benefits in IBD by promoting mucosal healing.
- Previous attempts to agonise the EP4 receptor have demonstrated early signals of clinical efficacy but have been limited by systemic safety.

Improved barrier repair & homeostasis
↓ permeability




Created with BioRender.com

### Progress

- **Ph1 study is ongoing**
  - Healthy volunteers study
  - SAD/MAD studies have progressed well with the fifth MAD cohort now completed
  - No concerning adverse events have been noted to date
  - Current additional cohorts which are underway within the First-in-Human study protocol are focused on demonstrating target engagement. This will generate supporting data to inform Phase 2 dose selection.
- **Ph2 enabling data package on track for 2H 2025**

Study link:
https://www.isrctn.com/ISRCTN70080074?q=nxera&filters=&sort=&offset=1&totalResults=2&page=1&pageSize=10

# FY2025 Objectives and beyond

Chris Cargill, President and CEO

05

# Priority objectives for FY2025

01 JPY 17 billion+ Net product sales (PIVLAZ® plus QUVIVIQ®)

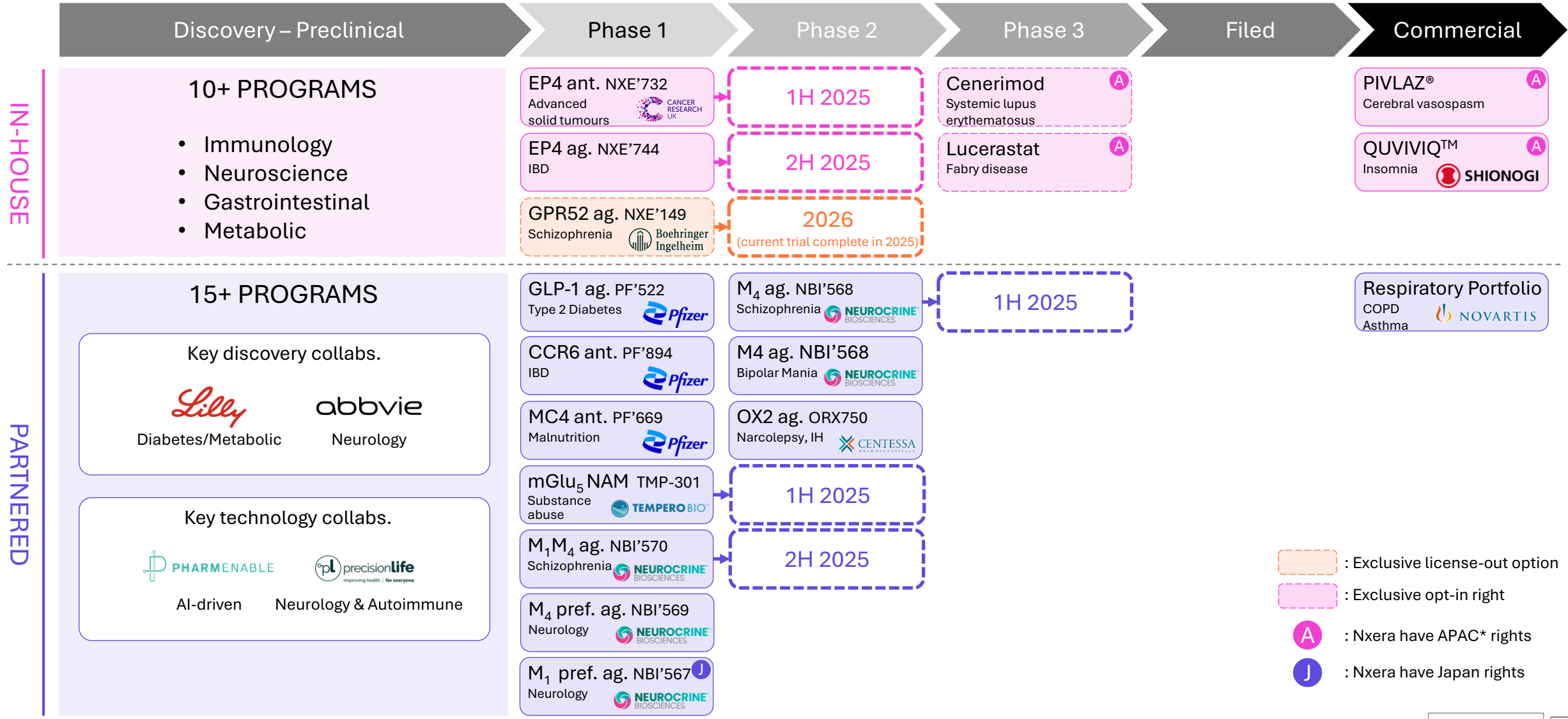
02 Acquire/in-license at least one late-stage medicine for Japan/APAC (ex-China)

03 Execute at least one new major partnership, and initiate at least one new in-house Ph.2 study

04 Investment in systems and applications for efficiency and scalability

05 Positive operating profit under IFRS (if GPR52 option is exercised)

# Major Pipeline Overview (with future projection)




Note: Pref. ag. : Preferring agonist

Respiratory Portfolio = Seebri®, Ultibro®, Enerzair® and Breezhaler® which is registered trademarks of Novartis AG.

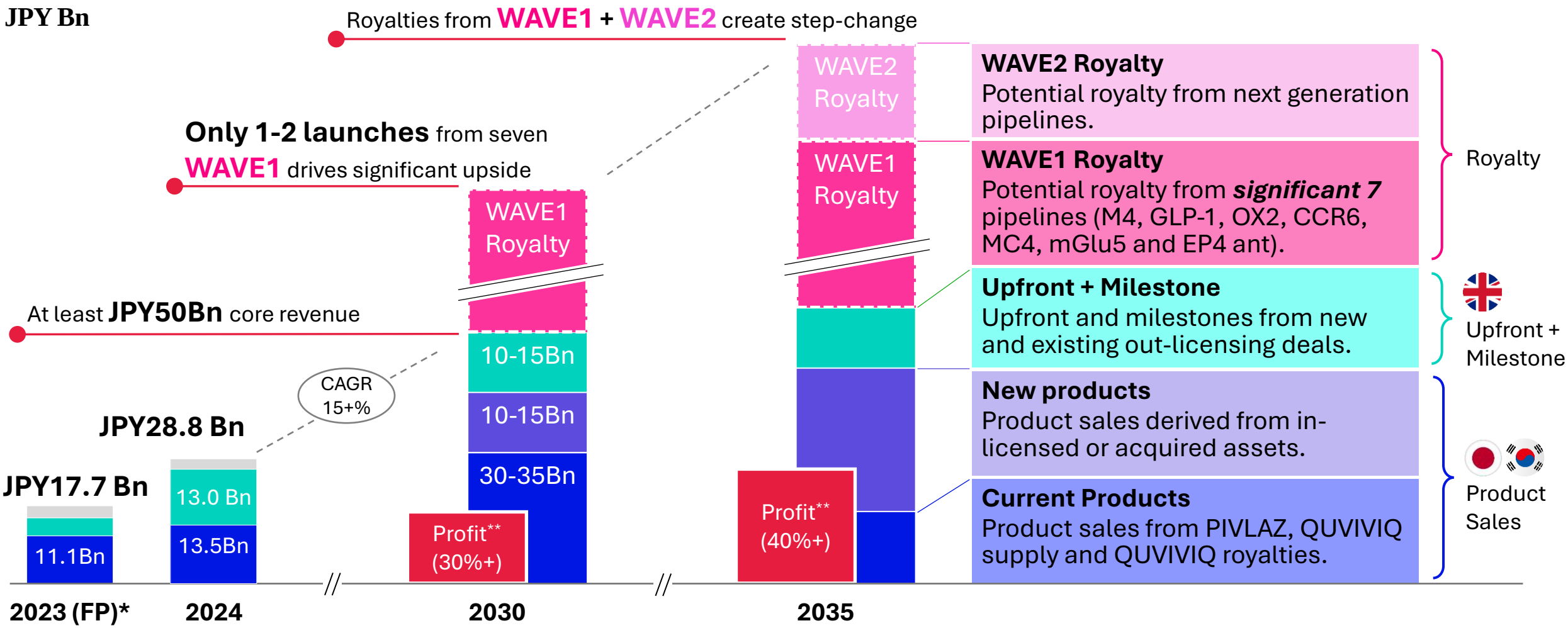
*APAC (ex-China) territory includes Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

# Our Wave 1 and Wave 2 programs are positioned across fast growing areas of healthcare

| | | WAVE1 (Potential Launch by 2030) | WAVE2 (Potential Launch by 2035) |
|---|---|---|---|
| Neurology | MARKET SIZE (2030) $120bn+ | TEMPERO BIO: P1 mGlu5 NAM *Substance Use Disorders*<br>CENTESSA PHARMACEUTICALS: P2 Ox2 agonist *Narcolepsy*<br>NEUROCRINE BIOSCIENCES: P2 M4 agonist *Schizophrenia*; P2 M4 agonist *Bipolar Mania*; P1 M1/M4 agonist *Schizophrenia* | CENTESSA PHARMACEUTICALS: PreC Ox2 agonists *Neuropsych-related sleep disorders*<br>NEUROCRINE BIOSCIENCES: P1 M4 pref. agonist; P1 M1 pref. agonist *Cognitive & psychosis -related disorders*<br>Nxera: P1 GPR52 agonist *Schizophrenia*<br>abbvie: Disc Multiple targets *Neurology* |
| Metabolic | MARKET SIZE (2030) $150bn+ | Pfizer: P1 GLP-1 agonist *T2D / Obesity*; P1 MC4 antagonist *Malnutrition* | Lilly: Disc Multiple targets *T2D/Obesity and Others* |
| Immunology / GI | MARKET SIZE (2030) $300bn+ | Pfizer: P1 CCR6 antagonist *IBD*<br>Nxera / CANCER RESEARCH UK: P1 EP4 antagonist + PD-L1 *Immune-oncology for Advanced Solid Tumors* | Nxera: P1 EP4 agonist *IBD* |
| | | **JPY250bn (max total royalty potential at peak)** | **Multi billion USD milestones and royalties** |

Source: EvaluatePharma, News Research, Internal Analysis

# Our 2030 vision is to build a high growth, highly profitable Japanese biopharma




Note: * Revenue values are proforma the acquisition of Idorsia Pharmaceuticals Japan and Korea and reflect annual product sales of PIVLAZ in 2023.
** WAVE1 and WAVE2 royalty is not included.

# Looking ahead to potential catalysts in 2025*

| PROGRAM | PARTNER | TIMING | EVENT |
|---|---|---|---|
| TMP-301 (mGlu5 NAM) | TEMPERO BIO | H1 2025 | Phase 2 study start in alcohol use disorder |
| Cenerimod (S1P1) / Lucerastat | idorsia | H1 2025 | Exclusive opt-in decision |
| NXE'732 (EP4 antagonist) | Nxera + CANCER RESEARCH UK | H1 2025 | Phase 2a study start in Advancing Solid Tumors |
| NBI'568 (M4 agonist) | NEUROCRINE BIOSCIENCES | H1 2025 | Phase 3 study start in Schizophrenia |
| NBI'568 (M4 agonist) | NEUROCRINE BIOSCIENCES | H2 2025 | Phase 2 study start in Bipolar Mania |
| NBI'570 (M1/M4 agonist) | NEUROCRINE BIOSCIENCES | H2 2025 | Phase 2 study start in Schizophrenia |
| NXE'744 (EP4 agonist) | Nxera | H2 2025 | Phase 2 study start in IBD |
| NXE'149 (GPR52 ag) | Nxera + Boehringer Ingelheim | H2 2025 | Phase 1b completion |
| NXE'732 (EP4 antagonist) | Nxera + CANCER RESEARCH UK | H2 2025 | Phase 1b topline data |
| ORX750 (OX2 agonist) | CENTESSA PHARMACEUTICALS | H2 2025 | Phase 2a data across NT1, NT2, and IH |
| Multiple discovery collaboration progress | abbvie Lilly | 2025 | Progression through discovery stage |
| NBI'567 (M1 ago) / NBI'569 (M4 ago) / NBI'570 (M1/M4 ago) | NEUROCRINE BIOSCIENCES | 2025 | Phase 1 data readout |
| New global out-licenses | | Anytime | Out licensing and/or discovery collabs |
| New Japan / APAC in-licenses | | Anytime | Acquire/in-license late-stage medicines |
| QUVIVIQ™ | | Anytime | APAC out-licensing deals |

* Partnered product progress is as already signaled or disclosed by partner

# Questions?

# Thank you

# Appendix

07

# Lead program, NBI'568 demonstrated positive phase 2 data in H2 2024

## Once-daily 20 mg dose showed efficacy and good safety/tolerability profile for schizophrenia patients

| | | | |
|---|---|---|---|
| Clinically meaningful and statistically significant efficacy (Once-daily 20 mg dose) | ➢ PANSS total score change | **-18.2** | Met primary and additional endpoints and demonstrated **efficacy on both positive and negative symptoms** |
| | ➢ PANSS total score change vs. Placebo | **-7.5 (p = 0.011)** | |
| | ➢ Effect size | **0.61** | |
| | ➢ Marder Factor score change vs Placebo: | | |
| | • Positive | **-3.0 (p=0.004)** | |
| | • Negative | **-1.9 (p=0.028)** | |
| Generally safe and well-tolerated across all doses tested | ➢ Treatment discontinuation rate due to adverse events across all NBI'568 arms | **5.0% (placebo: 4.3%)** | NBI'568 showed **safety and tolerability for all doses** |
| | ➢ GI and CV adverse event frequency (Cobenfy (BMS/Karuna): 3-5x (GI), ~4x (CV) vs. placebo) | **Similar to placebo** | |
| Rapidly advancing to Phase 3 development | ➢ Received successful milestone of Ph2 trial | **US$ 35 m** | **Expanding potential** of muscarinic agonist portfolio |
| | ➢ Ph3 clinical trial | **begin in H1 2025** | |
| | ➢ Additional Ph2 trial in Bipolar Mania | **begin in H2 2025** | |
| | ➢ **Advancing follow-on compounds** in muscarinic agonist portfolio | | |

Source: Presentation of Neurocrine Sciences (Aug.28 2024), KarXT for Schizophrenia draft evidence report (Nov. 28, 2023)

# Exclusive Opt-in Rights And ROFN/ROFR[1]

## Option to develop up to six clinical programs for Japan and APAC (ex-China) from Idorsia

| | Program | Mechanism of Action | Indication | Stage | Region |
|---|---|---|---|---|---|
| Exclusive Opt-in Right | Cenerimod | S1P1 receptor modulator | Systemic lupus erythematosus | Phase 3 | APAC (ex-China)[2] |
| | Lucerastat | Glucosylceramide synthase inhibitor | Fabry disease | Phase 3 | |
| ROFR /ROFN[1] | ACT-1004-1239 | ACKR3 / CXCR7 antagonist | Multiple sclerosis and other demyelinating diseases | Phase 2* | |
| | ACT-1014-6470 | C5aR1 antagonist | Immune-mediated disorders | Phase 1* | |
| | IDOR-1117-2520 | Undisclosed | Immune-mediated disorders | Phase 1* | |
| | ACT-777991 | CXCR3 antagonist | Recent-onset Type 1 diabetes | Phase 1* | |

[1] ROFN/ROFR - Right of first negotiation / Right of first refusal
[2] Territories include Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam
* Global Phase

# Core Operating Profit - Definition

## Core Operating Profit/Loss – a financial indicator closer to the reality of our business

### Operating Profit "Core"

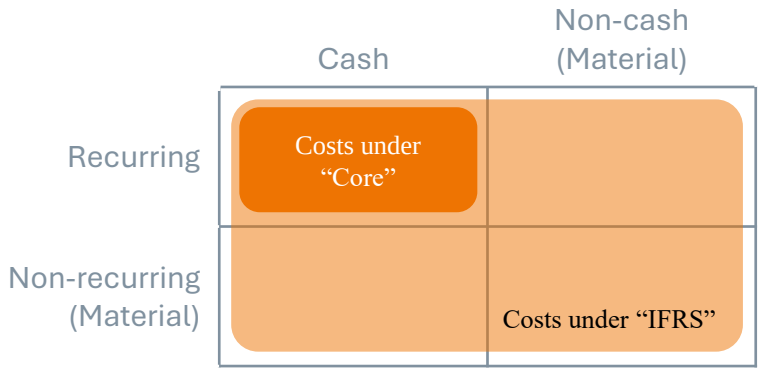
- Core Operating Profit/ Loss is a key financial indicator that highlights the underlying recurring cash generating capability of our business.
- Core Operating Profit/Loss is defined as IFRS Operating Profit + material Non-cash costs + material non-recurring costs
- Material Non-cash Costs include depreciation, amortization, share based payments and impairment.
- Material Non-recurring Costs include restructuring costs, M&A related professional fees and other material one-off items.

**+ Material Non-cash Costs**

(Depreciation, Amortization, Share based payments, Impairment…etc.)

**+ Material Non-recurring Costs**

(Restructuring costs and Other material one-off items…etc.)




### Operating Profit "IFRS"

- Financial results recorded and prepared in accordance with International Financial Reporting Standards (IFRS)

# Estimation of potential market size

## Multi-billion USD annual peak sales potential for our post-pre-clinical pipeline

| Category | Indication[2] | Number of Patients | Peak Sales | | Candidates |
|---|---|---|---|---|---|
| | | | Market Size | Individual Products | |
| Neuroscience | Dementia | ~55 million | $7.3 billion (2010) | $3.9 billion (2009/Aricept) | M1 ag, M1/M4 ag |
| | Schizophrenia | ~20 million | $20.7 billion (2011) | $5.7 billion (2013/Abilify) | M4 ag, M1/M4 ag, GPR52 ag |
| | Substance use disorders | ~10.4 million[1] | - - | - - | mGlu5 NAM |
| | Narcolepsy | ~3 million | $2.5 billion (2024) | $1.4 billion (2024/Xywav) | OX2 ag |
| Immunology | Cancer | ~42 million | $210.5 billion (2024) | $28.7 billion (2024/Keytruda) | EP4 ant |
| | IBD | ~10 million | $23.8 billion (2024) | $6.2 billion (2022/Humira) | CCR6 ant, GPR35 ag, EP4 ag |
| | Systemic Lupus Erythematosus | ~5 million | $2.7 billion (2024) | $1.9 billion (2024/Benlysta) | Cenerimod |
| Metabolism | T2DM/Obesity | ~420 million | $76.8 billion (2024) | $18.2 billion (2024/Ozempic) | GLP1 ag |
| | Anorexia | ~10 million | - - | - - | MC4 ant |
| Total | | | ~$344 billion/year | ~$66 billion/year | |

Source (Number of patients): World Health Organization, Evaluate Pharma, The European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA), Narcolepsy Network, Inc., The Lupus Foundation of America, GBD 2015 Disease and Injury Incidence and Prevalence Collaborators (October 2016). "Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015". Lancet. 388 (10053): 1545–1602 [1] The number of patients with drug addiction
Source (Peak Sales): Sales of each indications are extracted form Evaluate Pharma's data of sales by disease and sales by individual products (as of 25 December 2024). [2] Nxera may target one segment in the market for specific diseases

# Partnered pipeline (1/2)

| Compound | Target / Mechanism of Action | Modality | Indication | Partner | Disc. | PCC | Ph1 | Ph2 | Ph3 | App | Mkt |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Partnered** | | | | | | | | | | | |
| Seebri® Breezhaler® | LAMA | SME | COPD | NOVARTIS | | | | | | | |
| Ultibro® Breezhaler® | LAMA+LABA | SME | COPD | NOVARTIS | | | | | | | |
| Enerzair® Breezhaler® | LAMA+LABA+ICS | SME | Asthma | NOVARTIS | | | | | | | |
| ORAVI® | Antifungal agent miconazole | SME | Oropharyngeal candidiasis | Hisamitsu | | | | | | | |
| NBI-1117568 | Muscarinic M4 agonist | SME | Schizophrenia | NEUROCRINE BIOSCIENCES | | | | | | | |
| NBI-1117568 | Muscarinic M4 agonist | SME | Bipolar Mania | NEUROCRINE BIOSCIENCES | | | | | | | |
| NBI-1117569 | Muscarinic M4 preferring agonist | SME | Neurology diseases | NEUROCRINE BIOSCIENCES | | | | | | | |
| NBI-1117570 | Muscarinic M1/M4 agonist | SME | Neurology diseases | NEUROCRINE BIOSCIENCES | | | | | | | |
| NBI-1117567 | Muscarinic M1 preferring agonist | SME | Neurology diseases | NEUROCRINE BIOSCIENCES | | | | | | | |
| PF-07054894 | CCR6 antagonist | SME | Inflammatory bowel disease | Pfizer | | | | | | | |
| PF-07258669 | MC4 antagonist | SME | Malnutrition | Pfizer | | | | | | | |
| PF-06954522 | GLP-1 agonist | SME | Type 2 Diabetes | Pfizer | | | | | | | |
| (Not disclosed) | CGRP antagonist | SME | Neurology diseases | Pfizer | | | | | | | |
| (Not disclosed) | Multi target | SME/LME | Multiple indications | Genentech A Member of the Roche Group | | | | | | | |
| (Not disclosed) | Multi target | SME | Neurology | abbvie | | | | | | | |
| (Not disclosed) | Multi target | SME | Diabetes/Metabolic | Lilly | | | | | | | |

Note: SME = small molecule. LME = large molecule. Seebri®, Ultibro®, Enerzair® and Breezhaler® are registered trademarks of Novartis AG.

# Partnered pipeline (2/2)

| Compound | Target / Mechanism of Action | Modality | Indication | Partner | Disc. | PCC | Ph1 | Ph2 | Ph3 | App | Mkt |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Co-development** | | | | | | | | | | | |
| KY1051 | CXCR4 mAb | mAb | Immuno-oncology | sanofi | | | | | | | |
| (Not disclosed) | AI-Augmented Drug Discovery | SME | Neurology diseases | PHARMENABLE | | | | | | | |
| (Not disclosed) | Multi targe | SME/LME | Immune / Neurology diseases | precisionlife | | | | | | | |
| **Co-owned companies** | | | | | | | | | | | |
| TMP-301 | mGlu5 NAM | SME | Substance use disorders | TEMPERO BIO | | | | | | | |
| ORX750 | OX2 agonist (Oral) | SME | Narcolepsy Type 1/2, IH | CENTESSA / Orexia Therapeutics | | | | | | | |
| ORX142 | OX2 agonist (Oral) | SME | EDS in neurology | CENTESSA / Orexia Therapeutics | | | | | | | |
| ORX489 | OX2 agonist (Oral) | SME | Neurology | CENTESSA / Orexia Therapeutics | | | | | | | |

Note: SME = small molecule. LME = large molecule

# In-house pipeline

| Compound | Target / Mechanism | Modality | Indication | Partner | Disc. | PCC | Ph1 | Ph2 | Ph3 | App | Mkt |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **In-house Programs** | | | | | | | | | | | |
| PIVLAZ® | ETA antagonist | SME | Cerebral vasospasm | Nxera | | | | | | | |
| QUVIVIQ™ | Dual Orexin antagonist | SME | Insomnia | SHIONOGI | | | | | | | |
| NXE0048149 [1] | GPR52 agonist | SME | Neurology diseases | Boehringer Ingelheim | | | | | | | |
| NXE0039732 | EP4 antagonist | SME | Immuno-oncology | Nxera | | | | | | | |
| NXE0033744 | EP4 agonist | SME | Inflammatory bowel disease | Nxera | | | | | | | |
| NXE0027477 | GPR35 agonist | SME | Inflammatory bowel disease | Nxera | | | | | | | |
| (Not disclosed) | Muscarinic M1 agonist (JP) | SME | Neurology diseases | Nxera | | | | | | | |
| (Not disclosed) | SARS CoV-2 Mpro | SME | Coronaviruses | Nxera | | | | | | | |
| Multiple programs | Not disclosed | SME/LME | Neurology diseases | Nxera | | | | | | | |
| Multiple programs | Not disclosed | SME/LME | GI and Inflammatory diseases | Nxera | | | | | | | |
| Multiple programs | Not disclosed | SME/LME | Immunology diseases | Nxera | | | | | | | |
| **In-house Programs (No longer internally funded. Targeting academic / industrial partnership)** | | | | | | | | | | | |
| NXE'310 | SSTR5 agonist | Peptide | Hypoglycaemic disorders | Nxera | | | | | | | |
| NXE'097 | GLP-1 antagonist | Peptide | Hypoglycaemic disorders | Nxera | | | | | | | |
| NXE'023 | Dual GLP-2/GLP-1 agonist | Peptide | Intestinal failure/NASH | Nxera | | | | | | | |
| (Not disclosed) | Apelin agonist | Peptide | Pulmonary Arterial Hypertension | Nxera | | | | | | | |
| NXE'641 | Dual orexin antagonist | SME | Insomnia and sleep disorders | Nxera | | | | | | | |
| (Not disclosed) | PAR-2 mAb | mAb | Atopic Dermatitis/Pain | Nxera | | | | | | | |

Note: SME = small molecule. LME = large molecule. 1: Exclusive license-out option

# Clinical Trials

| Compound | MoA | Condition | Phase | Size | Patient | Start | Completion* | Last Update | Link (main/latest) | Link (others) |
|---|---|---|---|---|---|---|---|---|---|---|
| NBI-1117568 | M4 agonist | Schizophrenia | Ph2 | 210 | Yes | 2022-10-04 | 2024-07-10 | 2024-09-27 | NCT05545111 | - |
| NBI-1117569 | M4 preferring agonist | Neurology diseases | Ph1 | - | - | - | - | - | - | - |
| NBI-1117570 | M1/M4 agonist | Neurology diseases | Ph1 | - | No | 2024-03-11 | 2025-09-04 | 2024-10-30 | 2023-508814-40-00 | - |
| NBI-1117567 | M1 preferring agonist | Neurology diseases | Ph1 | - | - | - | - | - | - | - |
| PF-07054894 | CCR6 antagonist | Inflammatory bowel diseases | Ph1 | 27 | Yes | 2022-11-07 | 2026-01-14 | 2024-10-08 | NCT05549323 | NCT06327880<br>NCT04388878 |
| PF-07258669 | MC4 antagonist | Malnutrition | Ph1 | 14 | No | 2025-01-02 | 2025-02-11 | 2024-11-27 | NCT06706869 | NCT04628793<br>NCT05113940 |
| PF-06954522 | GLP-1 agonist | T2DM/Obesity | Ph1 | 122 | Yes | 2024-02-20 | 2024-12-31 | 2024-09-19 | NCT06279234 | NCT06393517<br>NCT06003777 |
| TMP-301 | mGlu5 NAM | Substance use disorders | Ph2 | 100 | Yes | 2024-11-14 | 2025-11-15 | 2024-12-19 | NCT06648655 | NCT06648668<br>NCT06025396<br>NCT03785054 |
| ORX750 | OX2 agonist | Narcolepsy Type 1/2, IH | Ph2 | 78 | Yes | 2024-12-23 | 2025-12 | 2024-12-31 | NCT06752668 | - |
| NXE0048149 | GPR52 agonist | Neurology diseases | Ph1 | up to 104 | No | 2023-02-20 | 2024-11-29 | 2024-04-18 | ISRCTN17231793 | - |
| NXE0039732 | EP4 antagonist | Immuno-oncology | Ph1<br>Ph2 | 150 | Yes | 2023-07-13 | 2026-09 | 2024-12-02 | NCT05944237 | - |
| NXE0033744 | EP4 agonist | Inflammatory bowel diseases | Ph1 | - | - | - | - | - | - | - |

*Primary Completion (Estimated)

# Exchange Rate, Intangible Assets and Non-core Costs

**Average exchange rate during period (actual)**

| | FY2024 | FY2023 | FY2022 |
|---|---|---|---|
| USD:JPY | 151.43 | 140.53 | 131.30 |
| GRP:JPY | 193.49 | 174.81 | 161.76 |

**Assumed exchange rate for key cost estimates**

| | FY2025 | FY2024 | FY2023 |
|---|---|---|---|
| USD:JPY | 152 | 140 | 143 |
| GRP:JPY | 193 | 172 | 166 |

**Intangible assets** (JPY mn)

| | Dec 31, 2024 | Dec 31, 2023 | Dec 31, 2022 |
|---|---|---|---|
| PIVLAZ® | 36,164 | 37,527 | - |
| Core technology | 8,365 | 8,466 | 8,217 |
| QUVIVIQ™ | 6,825 | 5,825 | - |
| Customer-related assets | 227 | 227 | 219 |
| Oravi® | 78 | 89 | 101 |
| Other | 252 | 157 | 40 |
| Total | 51,911 | 52,291 | 8,577 |

**Non-core costs (full year)** (JPY mn)

| | FY 2024 | FY 2023 | FY 2022 |
|---|---|---|---|
| Cost of sales adjustment | 2,401 | 1,812 | - |
| Amortization | 2,371 | 1,495 | 782 |
| M&A related costs | 1,220 | 1,263 | - |
| Depreciation | 1,613 | 983 | 563 |
| Share-based Payments | 1,396 | 844 | 542 |
| Restructuring costs | 28 | 53 | 533 |
| Impairment | - | - | - |
| Total | 9,029 | 6,450 | 2,420 |

# Glossary

| Basic Terminology/Technology | | |
|---|---|---|
| GPCR | G Protein-Coupled Receptor | There are about 800 types of GPCRs in the human body. While 400 of them are known to be potential drug targets, about 300 of them are not yet drugged |
| NxStaR™ | Stabilized Receptor | Nxera' proprietary technology to stabilize a GPCR by engineering a small number of single point mutations outside of the ligand-binding site. It enables to identify the structure of GPCRs to be used for SBDD drug discovery as well as antibody drug discovery as antigens |
| SBDD | Structure-Based Drug Design | A method to design drugs on a computer base based on the analysis of the three-dimensional structure of the drug target (e.g., protein receptor) |
| TPD | Targeted Protein Degradation | Drugs that promote the degradation of target proteins (e.g., receptors) in cells and aim for therapeutic effects by reducing disease-causing proteins |
| PAM | Positive Allosteric Modulator | A regulator that binds to unusual active sites (allosteric sites) on the receptor to increase the affinity and effect of the agonist |
| NAM | Negative Allosteric Modulator | A regulator that binds to an unusual active site on the receptor (allosteric site) and reduces the affinity and effectiveness of the agonist |
| Ag | Agonist | A therapeutic drug that binds to a receptor and activates an intracellular signaling system similar to biological substances |
| Ant | Antagonist | A therapeutic drug that suppresses biological reactions by binding to receptors and preventing them from binding to biological substances |
| PK | Pharmacokinetics | Research and testing on the relationship between drug dosage and blood concentration. Mainly describes the rate process of ADME |
| PD | Pharmacodynamics | Research and testing on the relationship between drug concentration and pharmacological effects |
| ADME | Absorption, Distribution, Metabolism and Excretion | A series of process in the absorption of drugs into the body, distribution within the body, metabolism in the liver and other organs, and excretion in the kidneys and other organs |
| POM | Proof of Mechanism | Proof of mechanism of action, mainly through biomarkers. It can suggest the possibility of efficacy in fewer cases than POC |
| POC | Proof of Concept | Proof of a therapeutic concept, primarily through clinical efficacy and safety |
| Ach | Acetylcholine | A neurotransmitter released from the peripheral parasympathetic and motor nerves to transmit nerve stimuli |
| IND | Investigational New Drug | Information packages for development candidates to be submitted to the U.S. Food and Drug Administration (FDA) at the time of initiation of clinical trials |
| Ph1 | Phase1 | A study in humans. The main purpose is to confirm the safety of the drug candidate mainly by healthy volunteers. |
| Ph2 | Phase2 | A study in humans. The main purpose is to confirm the efficacy of the drug candidates on a small scale (however, the number of patients varies greatly depending on the disease) |
| Ph3 | Phase3 | A study in humans. The main purpose is to determine the efficacy of the drug candidates on a large scale (however, the number of patients varies greatly depending on the disease) |
| NDA | New Drug Application | An application to the U.S. Food and Drug Administration (FDA) for approval to market a new drug |

| Disease/Drug | | |
|---|---|---|
| LAMA | Long Acting Muscarinic Antagonist | An inhalant that dilates bronchial tubes and improves respiratory function by inhibiting the action of acetylcholine receptors (M3), which increase parasympathetic nerves. |
| LABA | Long Acting Beta2-Agonist | An inhalant that improves respiratory function by stimulating sympathetic beta2 receptors to dilate the bronchi. |
| ICS | Inhaled Corticosteroid | An inhalant that suppresses airway inflammation to prevent coughing attacks and other symptoms caused by asthma, also promotes the action of beta 2 stimulants and improve airway hyperresponsiveness. |
| mCRPC | Metastatic Castration–Resistant Prostate Cancer | Cancer that has spread (metastasized) beyond your prostate gland and for which hormone therapy is no longer effective in stopping or slowing the disease. |
| COPD | Chronic Obstructive Pulmonary Disease | A group of diseases that causes damage to the bronchi and lung due to smoking or inhalation of toxic substances, resulting in breathing problems. |
| AD | Alzheimer's Disease | Alzheimer's disease is a progressive neurologic disorder that causes the brain to shrink (atrophy) and brain cells to die, the most common cause of dementia . |
| DLB | Dementia with Lewy Bodies | Protein deposits, called Lewy bodies, develop in nerve cells in the brain regions involved in thinking, memory and movement (motor control), the second most common type of dementia. |

# Locations

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