

# Nxera Pharma

## FY2025 Financial Results

12-month period ended December 31, 2025

13 February 2026 | 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 FY2026 Objectives and beyond
- 06 Appendix





# Financial Results

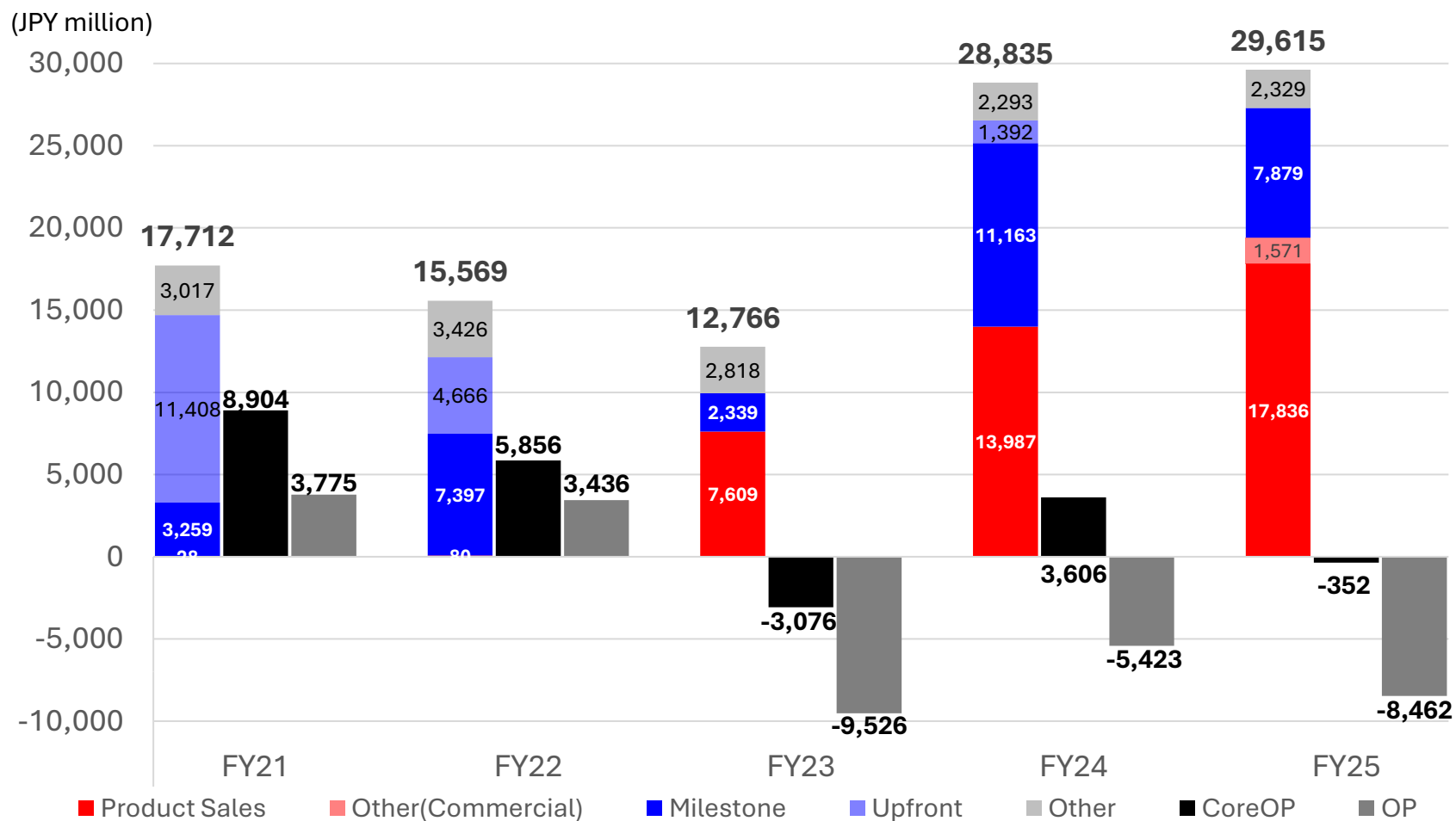
Hironoshin Nomura, CFO

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# Key financial results

While the commercial business grew, milestones decreased year-on-year, resulting in a core operating loss



## Progress in 2025



- Multiple milestone receipts from Neurocrine, Centessa, Lilly, AbbVie, etc.
- Down YoY due to the absence of the prior-year large M4 agonist Phase 2 success milestone



- 39% revenue growth (YoY)
  - Pivlaz: +7% YoY
  - Quviviq: +224% YoY





- R&D spend up in platform business on progress across three in-house clinical
- SG&A down in commercial business, driven by Pivlaz sales cost decrease



# Breakdown of 2025 results

Strong profitability growth in the commercial business; accelerated clinical-trial investment in the platform business

(JPY million)	 Platform*1		 Commercial*2		=	Consolidated P&L (Core)		+	Non-core costs	=	Consolidated P&L (IFRS)	
		(YoY)		(YoY)			(YoY)					(YoY)
<b>Revenue</b>	10,207	-31%	19,408	+39%		29,615	+3%		Total : 8,110		29,615	+3%
<b>Cost of Sales</b>	2,111	-22%	6,022	+149%		8,133	+59%		<b>A</b> Amortization (1,789)		8,198	+8%
<b>SG&amp;A</b>	4,940	+15%	5,480	-16%		10,420	-4%		<b>B</b> Other (3,080)		15,225	-5%
<b>R&amp;D</b>	11,669	+26%	1,352	+9%		13,022	+24%		<b>B</b> Other (1,444)		14,466	+22%
<b>Other income</b>	1,615	+344	(7)	+15		1,608	+360		<b>C</b> (1,797)		(189)	-1,377
<b>OP/Core OP</b>	<b>(6,899)</b>	<b>-6,745</b>	<b>6,547</b>	<b>+2,787</b>		<b>Core OP (352)</b>	<b>-3,958</b>				<b>OP (8,462)</b>	<b>-3,038</b>

**A** Amortization of intangible assets (currently relates to PIVLAZ® and QUVIVIQ®).

**B** Amortization of other intangible assets (e.g. IP), depreciation (e.g. laboratory equipment), share-based payments and other restructuring costs.

**C** Restructuring costs and impairment losses

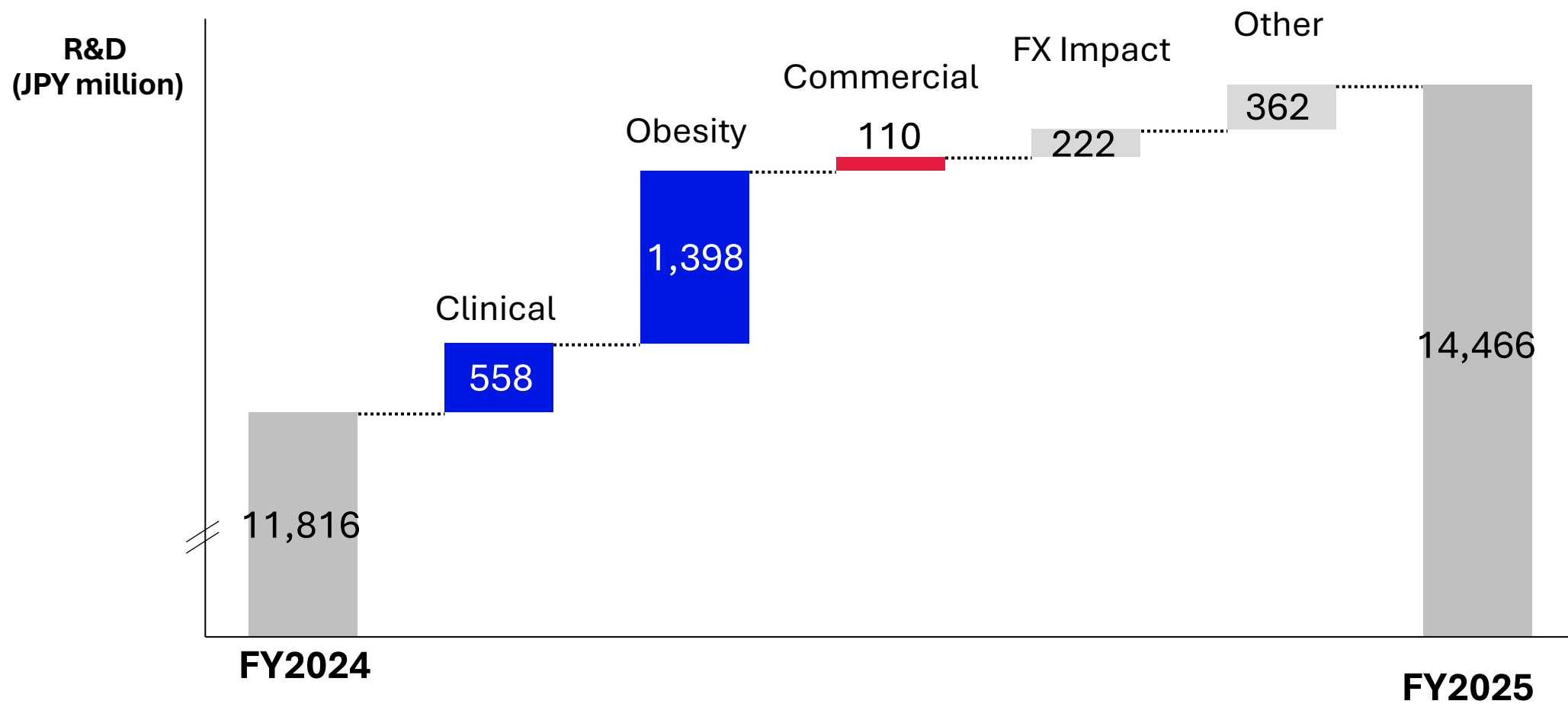
\*1 = Nxera Pharma Co. Ltd. (formerly Sosei Group Corporation) + Nxera Pharma UK Ltd (formerly Heptares Therapeutics Ltd.) + Sosei K.K. (ex -Nxera Pharma Basel branch)

\*2 = Nxera Pharma Japan (formerly Idorsia Pharmaceuticals Japan) + Nxera Pharma Korea (formerly Idorsia Pharmaceuticals Korea) + Nxera Pharma Basel branch



# Analysis of changes in R&D expenses

Clinical Development and Increased Investment Focus on Obesity as Key Drivers of Growth







# Operational Highlights

Chris Cargill, President and CEO

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## Recap of FY2025 Priority Objectives

01

JPY 17 billion+ Net product sales  
(PIVLAZ<sup>®</sup> plus QUVIVIQ<sup>®</sup>)



JPY17.8Bn

02

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



Vamorolone  
In-licensing (Jan)

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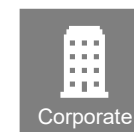
Execute at least one new major partnership,  
and initiate at least one new in-house Ph.2  
study



EP4 Antagonist  
Initiation of Ph2

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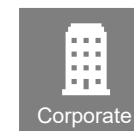
Investment in systems and applications  
for efficiency and scalability



Investment  
Executed as planned

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



Profit missed as  
option not exercised



Both sides of the business continue to advance rapidly

## Drug Discovery Platform



### Clinical Asset

	Active Programs	Changes in 2025
Phase 3	2*	+2
Phase 2	5	+2
Phase 1	5	-3 (moved to Ph2)

### Major Partners



abbvie

Lilly



## Commercial



### Products

	2025 Sales (Actual : JPY)	Changes in 2025 (Actual : JPY)
PIVLAZ®	13.5Bn	+7%
QUVIVIQ®	4.3 Bn	+224%

### Late-stage assets

Vamorolone

New

Candidate drug for DMD. Already approved in US and Europe.

Lucerastat

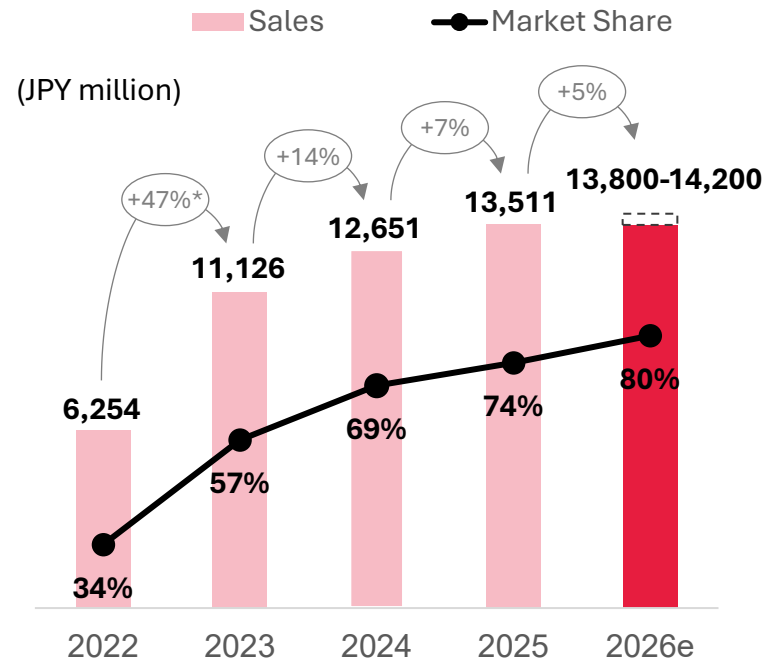
Candidate drug for Fabry disease. Nxera has exclusive opt-in rights.

On track to continue growth trajectory throughout 2026

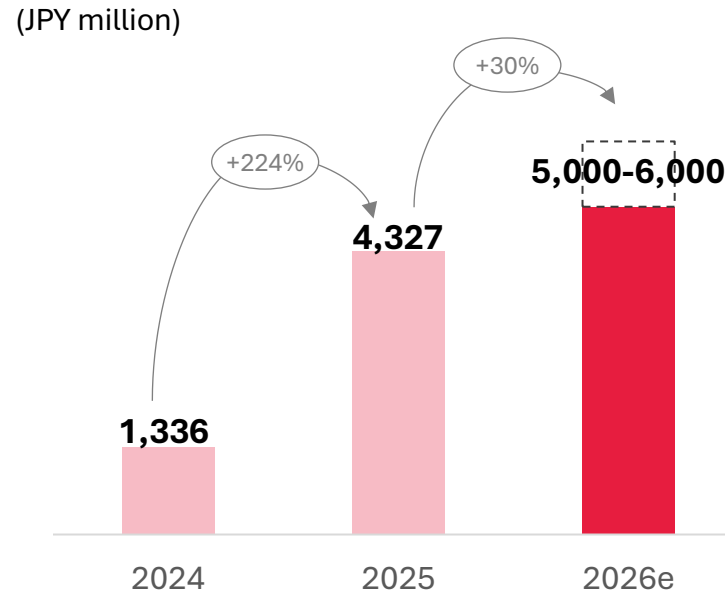


# Commercial Business

Two marketed products continue to grow, with a new product launch in early 2026 to support the next phase

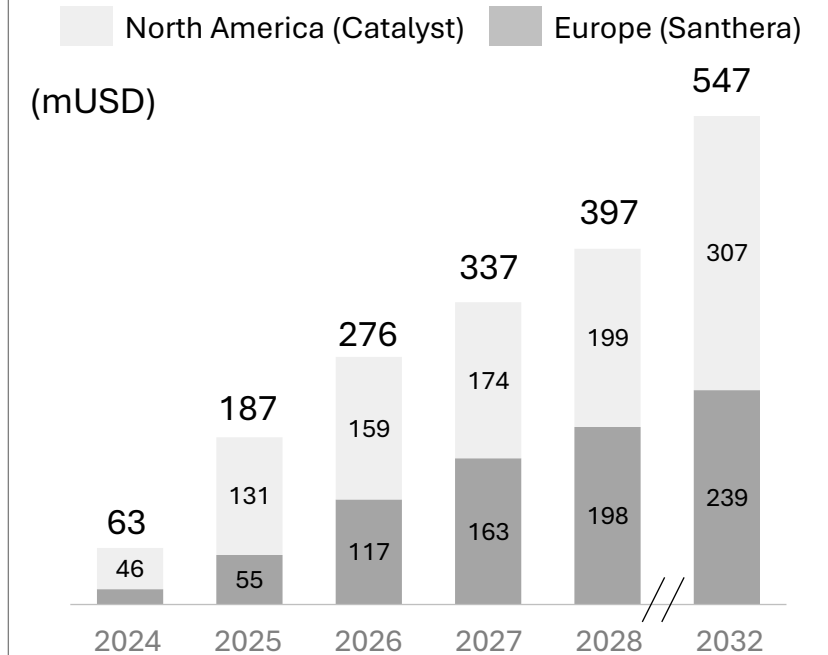


A “practical guide to clazosentan administration” is scheduled for release in the first half of 2026



Shionogi will be responsible for sales.  
Nxera hold the rights to product supply and royalties

## Vamorolone

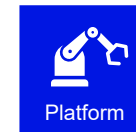


Potential to replace existing steroid therapy  
Estimated sales synergy with Pivlazz® of ~70%



# Platform Business

Partner-led development progressing well; strong phase 1 readouts for in-house programs



## Muscarinic Agonist Portfolio

Program	Target Disease	Phase
Direclidine	Schizophrenia	Phase3
	Bipolar disorder	Phase2
NBI'570	Schizophrenia	Phase2
NBI'569	AD's Psychosis	Phase1
NBI'567	AD	Phase1
	LBD	

First phase 3 readout for direclidine expected in 2027

Royalty: high single digits to mid-teens;  
Total milestones: up to \$2.6bn

Lead asset cobenfy peak sales expected to exceed JPY600bn



## Orexin Agonist Portfolio

Program	Target Disease	Phase
ORX750	NT1/NT2/IH	Phase2
ORX142	Neurological disorders	Phase2
ORX489	Neurological disorders	-

ORX750 to enter a registrational program in 1H 2026

Royalty: low single digits  
Development and sales milestones

ORX750 peak sales expected to exceed ¥200bn

## GPR52 ago | EP4 ago

### Licensing activities in progress

Program	Target Disease	Phase
NXE'149	Schizophrenia	Phase1
NXE'744	IBD	Phase1

Phase 1 completed successfully  
Phase 2 ready to initiate

In discussions with multiple partners for a 2026 license deal

NXE'744 showed early efficacy signals in an indomethacin challenge study

## EP4 antag



### Under development in-house

Program	Target Disease	Phase
NXE'732	Solid Cancer	Phase2

Ongoing phase 2 readout for NXE'732 expected in 2027

Nxera retains global rights

NXE'732 showed early efficacy signals, including two partial responses



# Major Pipeline Overview



**Vamorolone**  
Duchenne Muscular Dystrophy


**Lucerastat**  
Fabry disease

**PIVLAZ®**  
Cerebral vasospasm

**QUVIVIQ™**  
Insomnia




IN-HOUSE

 Best-in-class, focused on obesity and metabolic diseases

**EP4 ag. NXE'744**  
IBD

**GPR52 ag. NXE'149**  
Schizophrenia


**EP4 ant. NXE'732**  
Advanced solid tumors




*Develop programs in-house up to a certain stage to enhance their value, then out-license them to partner companies—while retaining rights for Japan (and other territories) for selected indications.*


PARTNERED

Key discovery collabs


  
Diabetes/Metabolic

  
Neurology


**M<sub>1</sub>M<sub>4</sub> ag. NBI'569**  
Alzheimer's psycho




**M<sub>1</sub> ag. NBI'567**  
AD Cognition\*/LBD




**MC4 ant. PF'669**  
Malnutrition



**M<sub>4</sub> ag. NBI'568**  
Bipolar Mania




**M<sub>1</sub>M<sub>4</sub> ag. NBI'570**  
Schizophrenia




**OX2 ag. ORX750**  
Narcolepsy, IH



**OX2 ag. ORX142**  
Neurology




**M<sub>4</sub> ag. NBI'568**  
Schizophrenia




Other

**Cenerimod**  
SLE



**Respiratory Portfolio**  
COPD / Asthma







# Japan/APAC Commercial Business

Toshihiro Maeda, Chief Operating Officer (COO) and  
President of Nxera Pharma Japan

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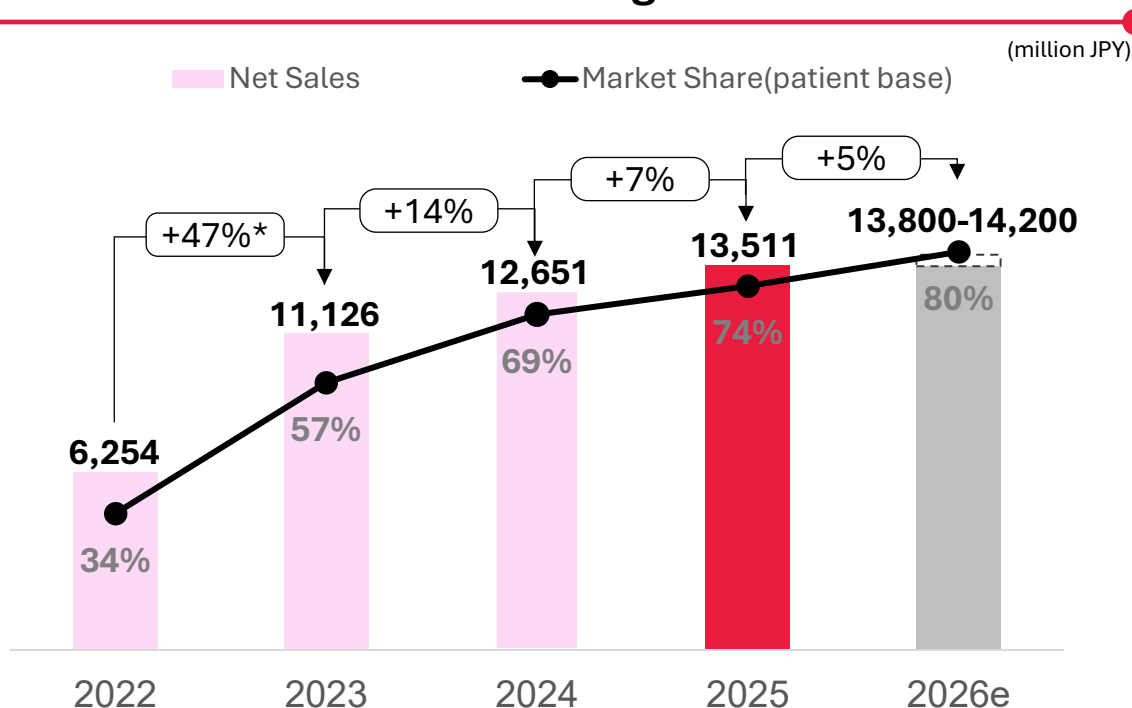


# PIVLAZ® (clazosentan, an endothelin A antagonist)

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



## PIVLAZ® sales growth



## 2025 PIVLAZ® highlights

- ✓ **25,470** patients were treated by PIVLAZ® since the launch to Dec 2025.
- ✓ **103** abstracts were presented at annual congress of STROKE2025
- ✓ Academic society drafted "Practical Guide to the Administration of Clazosentan", which would be published in Mar-2026

Pivlaz® is now the clear Standard of Care (SoC) in Japan

Source: MDV DPC hospital data

\*: Comparison of 2-4Q of 2022 and 2023,



# QUVIVIQ® (daridorexant, dual orexin antagonist “DORA”)

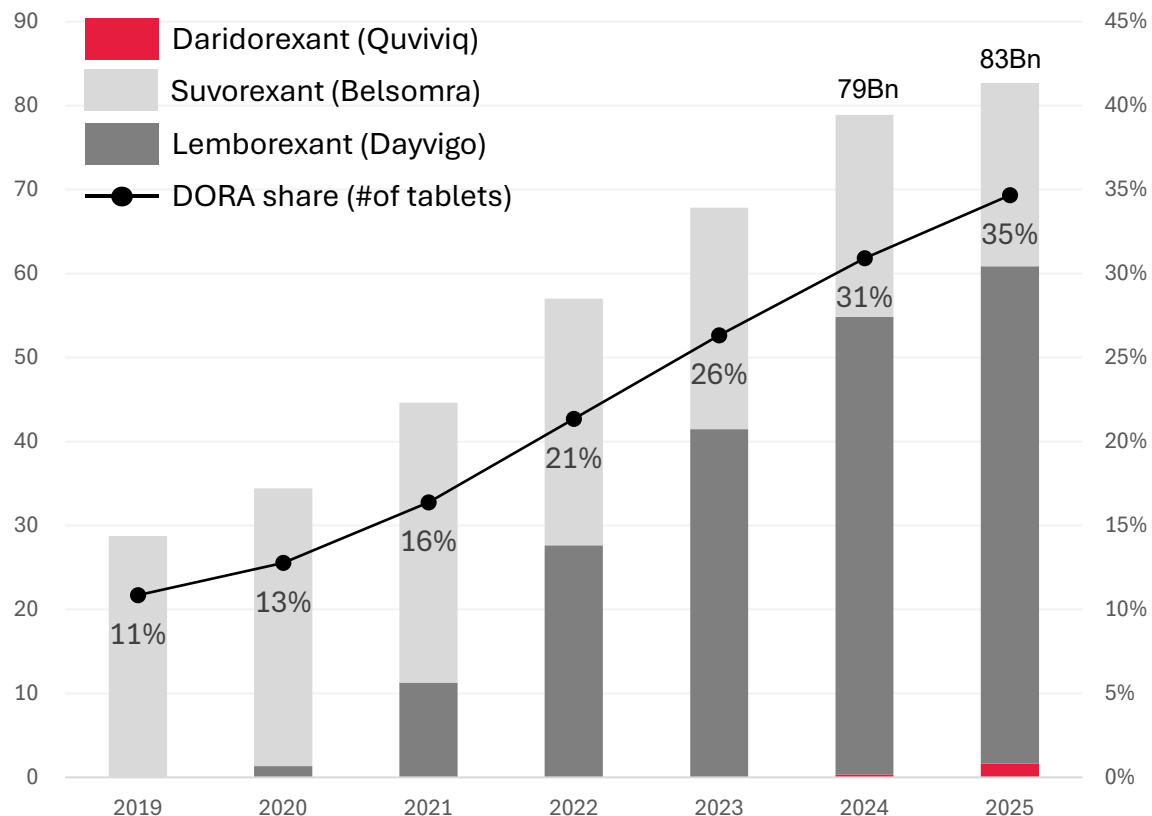
DORA is rapidly establishing its position in the treatment paradigm for insomnia



## Domestic Market Size for DORA

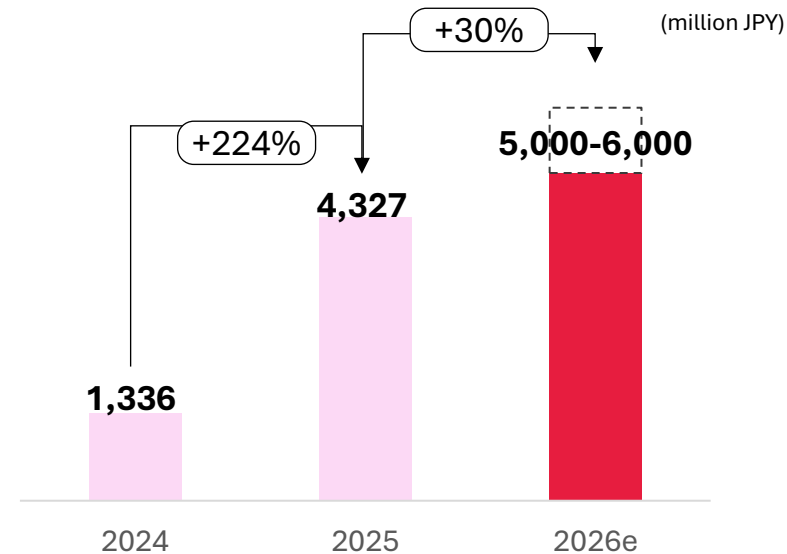
## QUVIVIQ® Annual Sales and Growth Rate

(Bn JPY)



5.0 – 6.0 Bn JPY

+30%





# QUVIVIQ® Business structure

Royalty profits initiated and supply margin expected in a few years

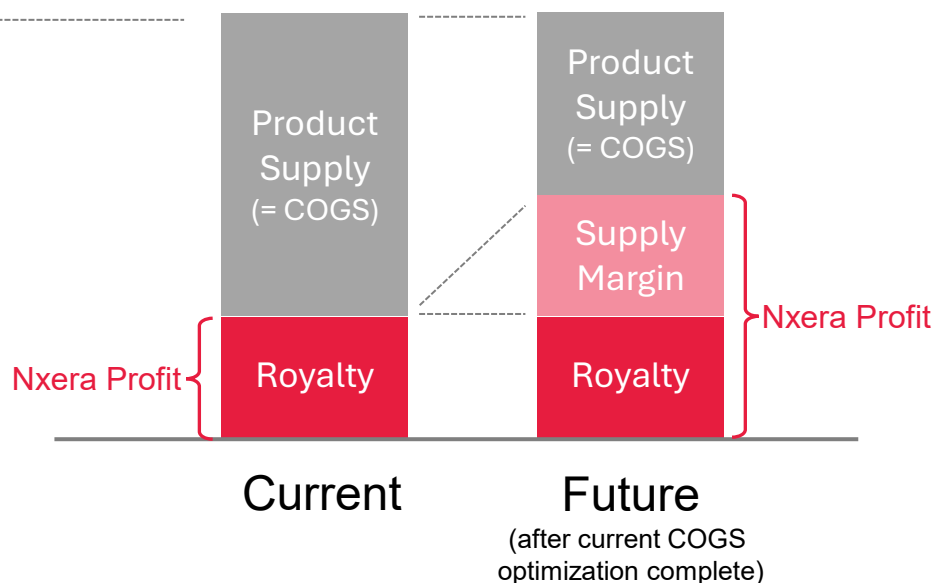
## Sales structure

Product net sales

Royalty +  
Product supply  
sales



## Profit structure for Nxera



## Supply chain optimization

**Comprehensive strategy to optimize the end-to-end supply chain**

*Achievements as of today*

- ✓ Establish Nxera independent supply chain from the licensor
- ✓ Regulatory approval on 2<sup>nd</sup> API source in October

*Future plan*

- ✓ Achieve further cost optimization on raw materials
- ✓ Optimize drug product and packaging sourcing



# Announced: In-licensing of vamorolone (AGAMREE®) for DMD

There is no established therapy for DMD other than corticosteroids in Japan



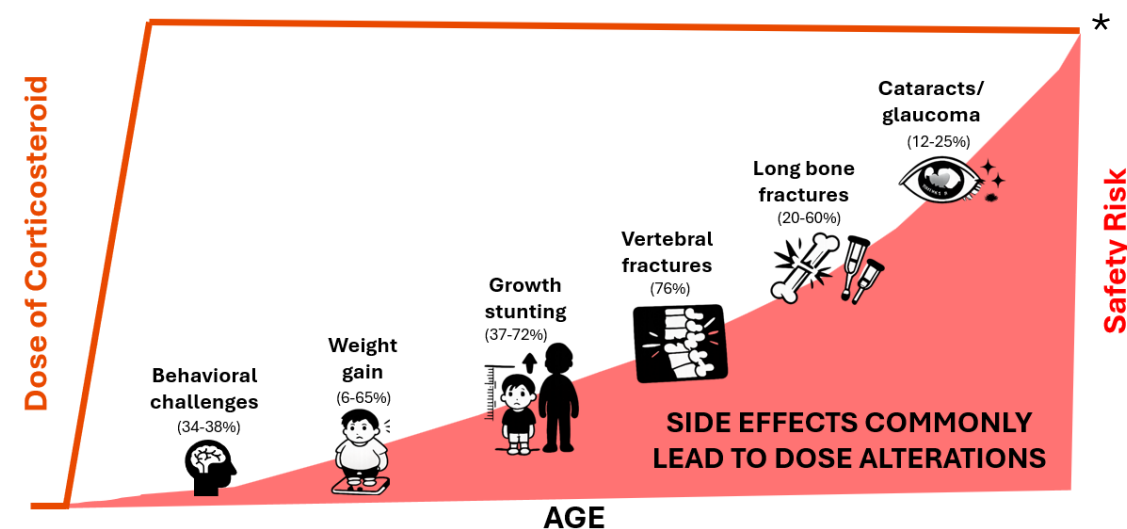
## Vamorolone (AGAMREE®)

- First-in-class drug candidate that binds to the **same receptors as corticosteroids** but modifies the downstream activity of the receptors
- Nxera has the development rights for **Japan, South Korea, Australia and New Zealand**
- DMD treatment is concentrated in a limited number of centers and there is approximately **70% sales synergy with PIVLAZ®**



## Duchenne Muscular Dystrophy (DMD)

- DMD is a rare and life-threatening neuromuscular disorder
- Characterized by progressive muscle dysfunction leading to ambulation loss, respiratory failure, heart issues and premature death
- No efficacious therapy apart from corticosteroids, however they present many severe adverse events





# Vamorolone (AGAMREE®) addresses the need for a tolerable steroid

Compared with conventional corticosteroid therapy, the risk of treatment-related adverse events is reduced

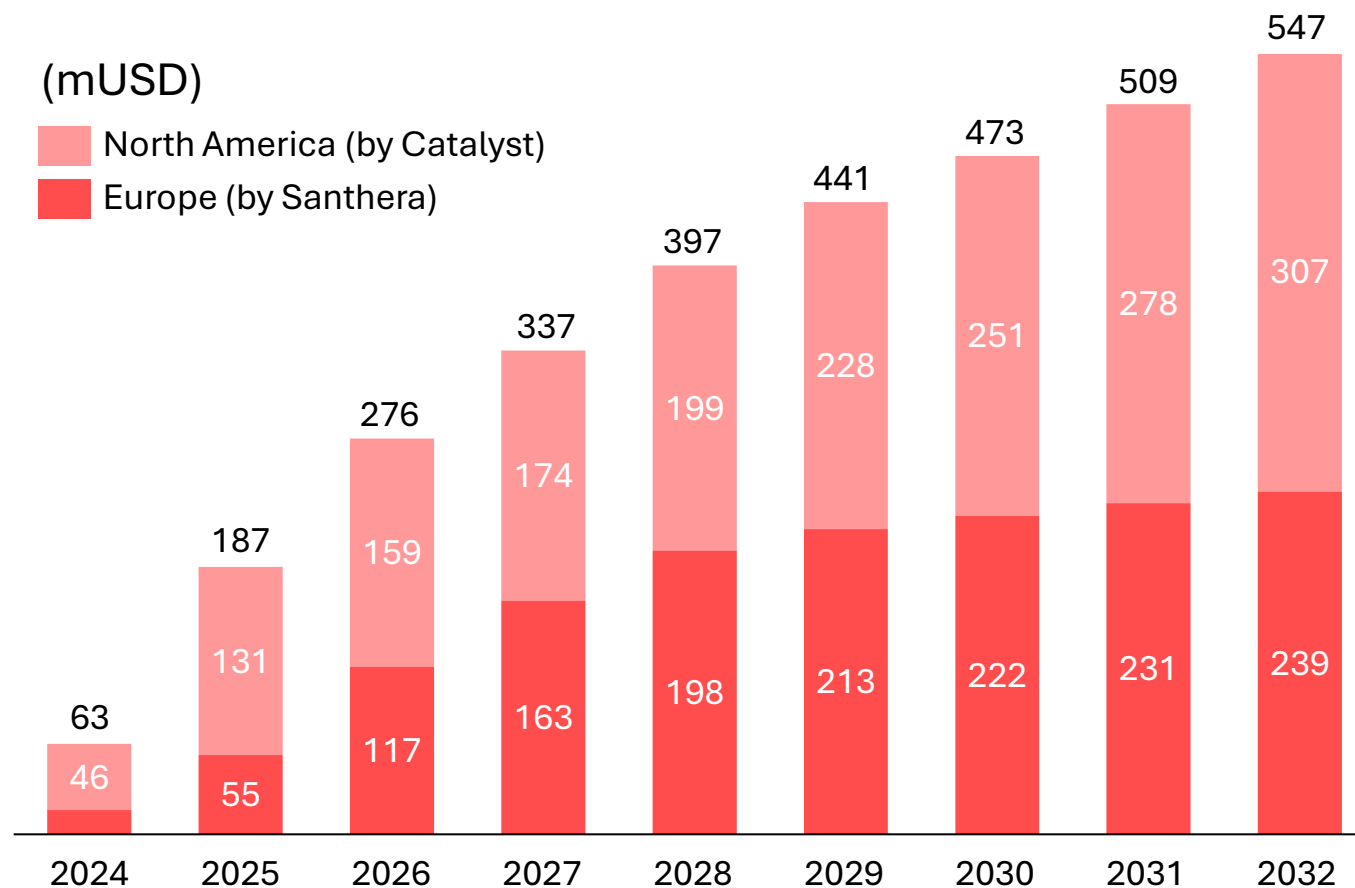


- Vamorolone confronts the limitations of standard corticosteroid therapy
- Topline data from the recent GUARDIAN clinical study showed **durable efficacy** and **markedly improved safety** of vamorolone vs. standard corticosteroids
- Study demonstrated reduction of steroid-associated adverse events related to:
  - Growth – *normal growth maintained ( $p < 0.0001$ )*
  - Bone health – *lower vertebral fracture rate ( $p = 0.0061$ )*
  - Eye health – *lower incidence of cataracts ( $p < 0.015$ ) and no cases of glaucoma*
- Reduction of side effects allows patients **to maintain treatment**

## Consensus sales forecast of vamorolone in other countries

(mUSD)

- North America (by Catalyst)
- Europe (by Santhera)



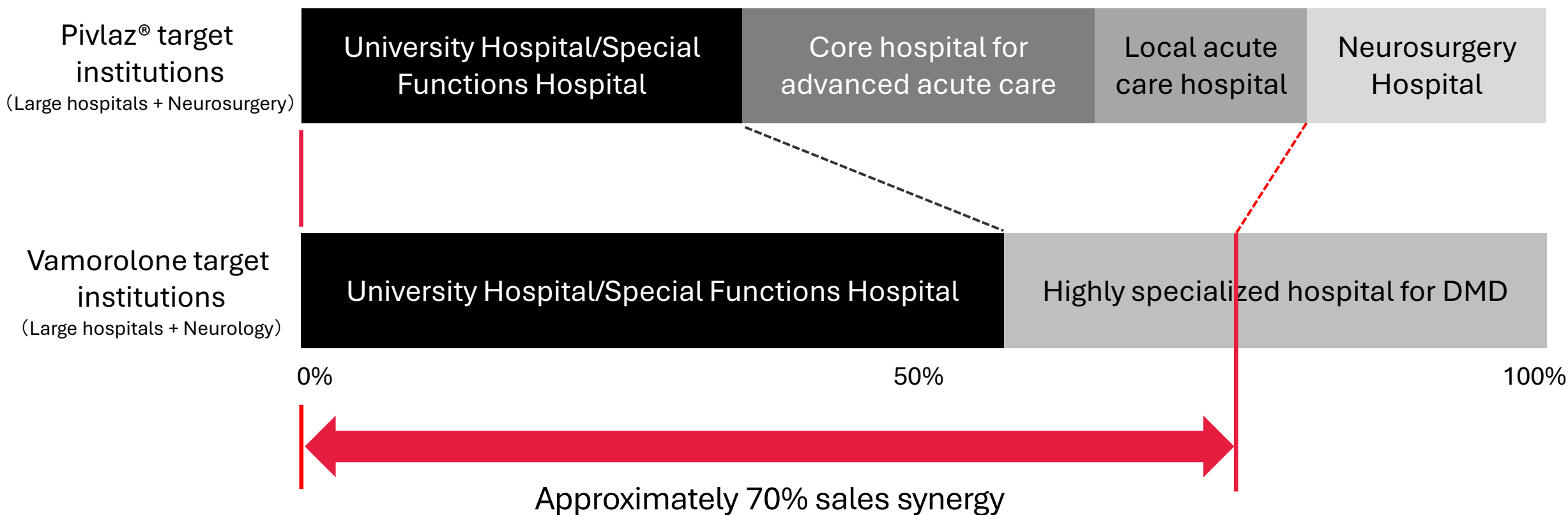


# Synergy with Pivlaz

DMD treatment is concentrated in a limited number of centers and there is approximately 70% commercial overlap with PIVLAZ, creating significant sales synergies



Proportion of prescription volume by hospital







# R&D Progress

Dr. Patrik Foerch, Chief Scientific Officer (CSO) and  
President of Nxera Pharma UK

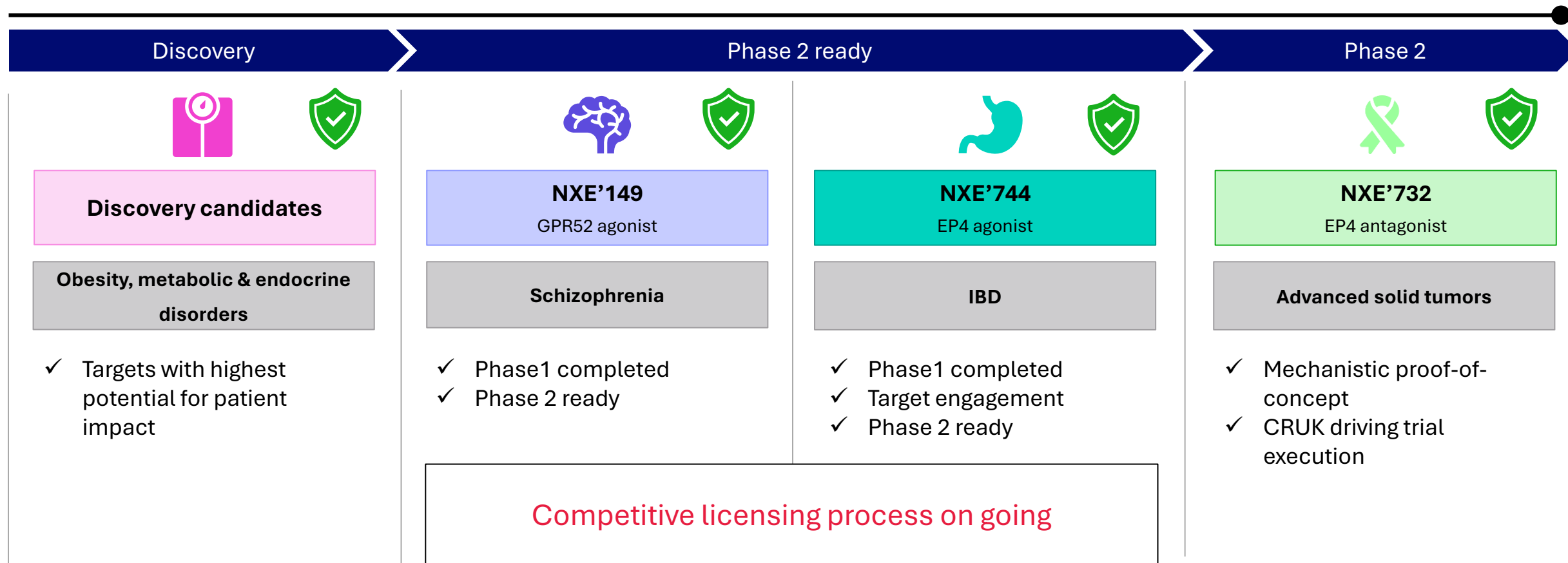
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Renewed R&D focus where the science is strongest and the opportunity is greatest



## IN-HOUSE PORTFOLIO - R&D FOCUS AND PROGRAM PRIORITISATION



R&D focus on highest potential opportunities



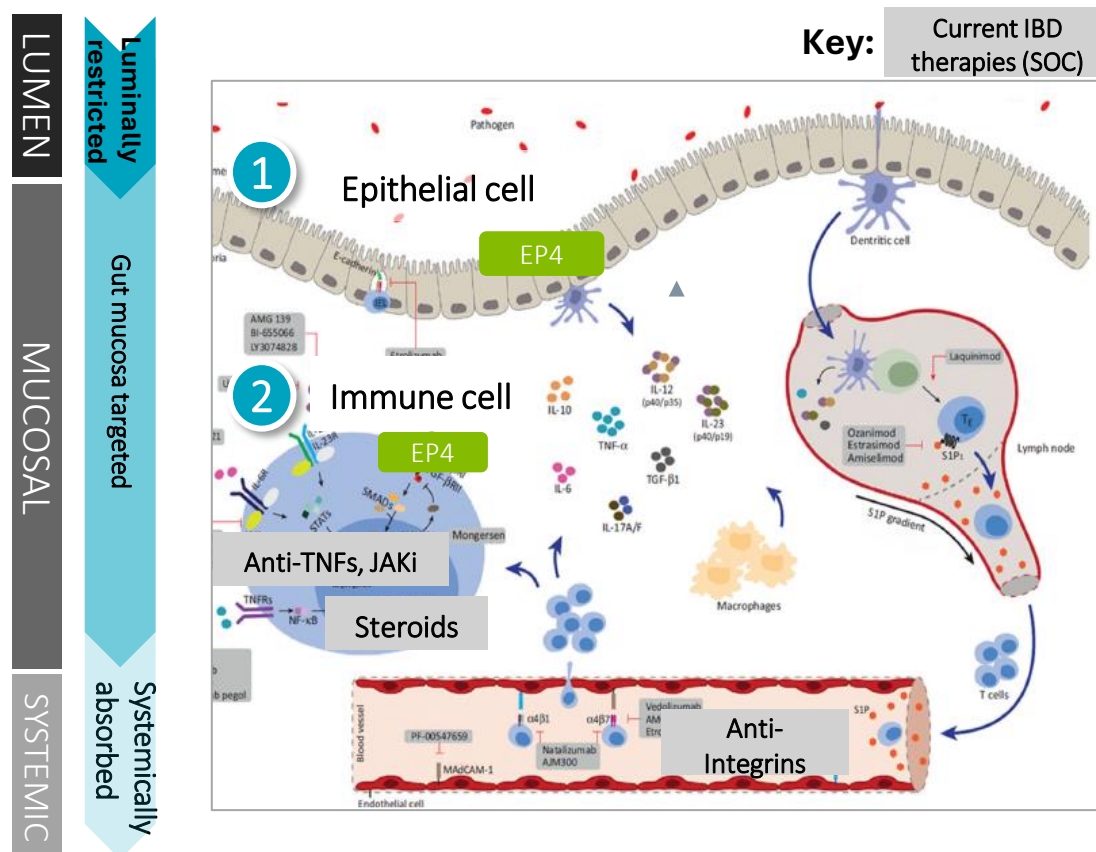
# NXE'744: EP4 agonist for IBD\* – target engagement & Phase 2 ready

A first-in-class GI-targeted agent to promote mucosal healing in IBD



## EP4 AGONIST OFFERS A DIFFERENTIATED MOA TO CURRENT SOC:

*Modulation of barrier homeostasis and inflammatory axis positions EP4 as an attractive MOA for IBD therapy*



- All elements of the first-in-human study have now completed dosing in the clinic
  - **SAD/MAD studies are complete** with no concerning adverse events and no systemic exposure observed
  - **Gut restricted profile confirmed** by high gut tissue concentrations measured following oral dosing
  - **UC patient cohort has completed dosing** (n=6) with interim analysis confirming high gut tissue concentration.
  - **Indomethacin challenge cohort complete**, interim analysis complete with no need to increase subjects and final data read-out by March 2026
  - Preliminary data analysis demonstrates a **highly significant ~50% reduction in indomethacin induced permeability** in the NXE'744 treatment group; these data confirm **target engagement in the small intestine**

\*inflammatory bowel disease

Study link:

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





# NXE'149: GPR52 agonist for schizophrenia – Phase 2 ready

A novel first-in-class mechanism to treat positive, negative & cognitive domains of schizophrenia

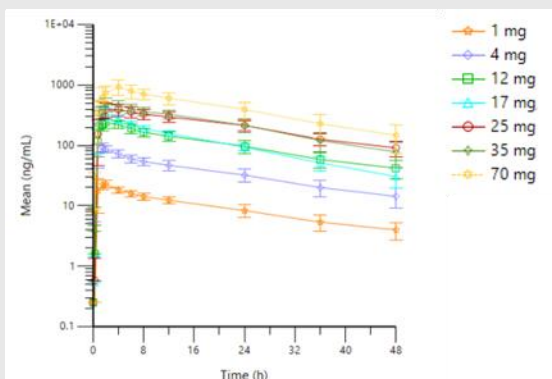
## Phase 1 highlights:

- ✓ Safe and well tolerated
- ✓ Human PK showed low variability and consistent with once daily dosing
- ✓ High level of central penetration
- ✓ Pharmacodynamic measures provide evidence of engagement of brain circuitry relevant to the treatment of schizophrenia and related disorders

## Phase 2 enablement:

- 3 month GLP toxicology in 2 species
- 2 species EFD completed
- Metabolite characterisation complete
- Drug substance and drug product available for phase 2 start

### SAD PK data



### EEG and ERP measures

- NXE'149 clearly engages frontotemporal circuitry underlying the MMN and ASSR responses, both of which are reproducible biomarkers in schizophrenia
- Resting state EEG data suggest increased arousal on day 10 of treatment

### Cognition

Cogstate assessment demonstrated improvements in cognitive performance across doses on day 10 of treatment

General cognitive composite	Dose 1	Dose 2	Dose 3	Dose 4
Attention/Executive Function	0.89	1.5	0.69	0.64
General Cognition	1.1	0.84	0.77	0.55

Standardized differences between each dose of NXE'149 compared to placebo





# NXE'732: EP4 antagonist is our novel immunotherapy for solid tumors

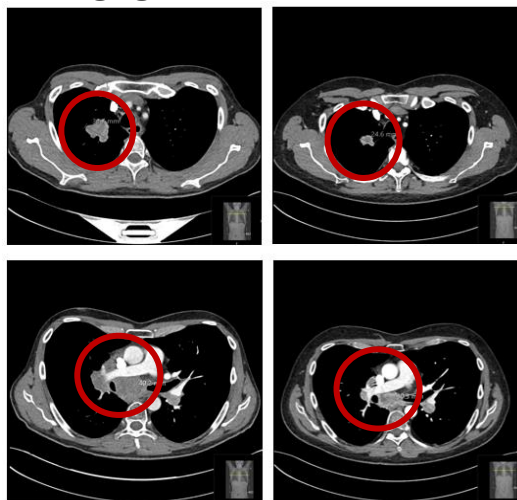
Phase 2a expansion in process in combination with atezolizumab

## Disease Rationale

- When EP4 is activated, it dampens immune responses and promotes tumor growth
- EP4 antagonism is a highly attractive mechanism supported by recent clinical data for ONO-4578 in gastric cancer
- NXE-732 is designed to deliver **high potency, selectivity, and safety**

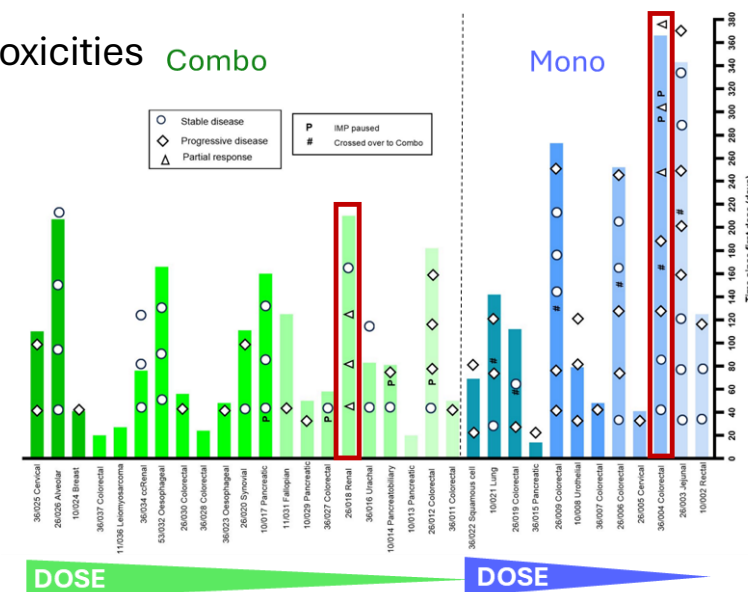
## Phase 1 trial results

- The emerging data for NXE-732 points to a potential best-in-class profile
- Two partial responses were observed in MSS CRC and anti-PD-L1 resistant ccRcc in the combination arm, with meaningful tumor shrinkage of over 30% demonstrated
- Target engagement confirmed and no dose-limiting toxicities



Baseline

3 months

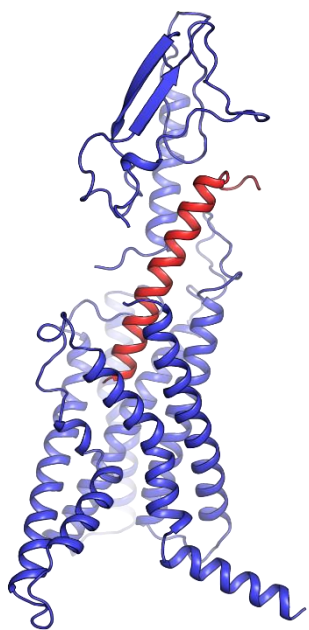


Phase 2a expansion study underway in **MSS Colorectal** (PIK3CA, HER2± others),  
**Gastric/GOJ Adenocarcinoma, Renal (ccRCC), Prostate (CRPC)**

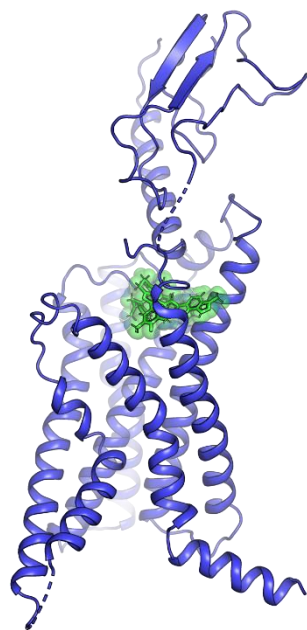


We can make a huge impact by leveraging our GPCR expertise in the areas of highest unmet medical need: next-generation small molecules for obesity, metabolic and endocrine disorders

## Unparalleled GPCR SBDD capabilities





Structure of GLP1-R  
bound to **peptide**



Structure of GLP1-R  
bound to **small molecule**

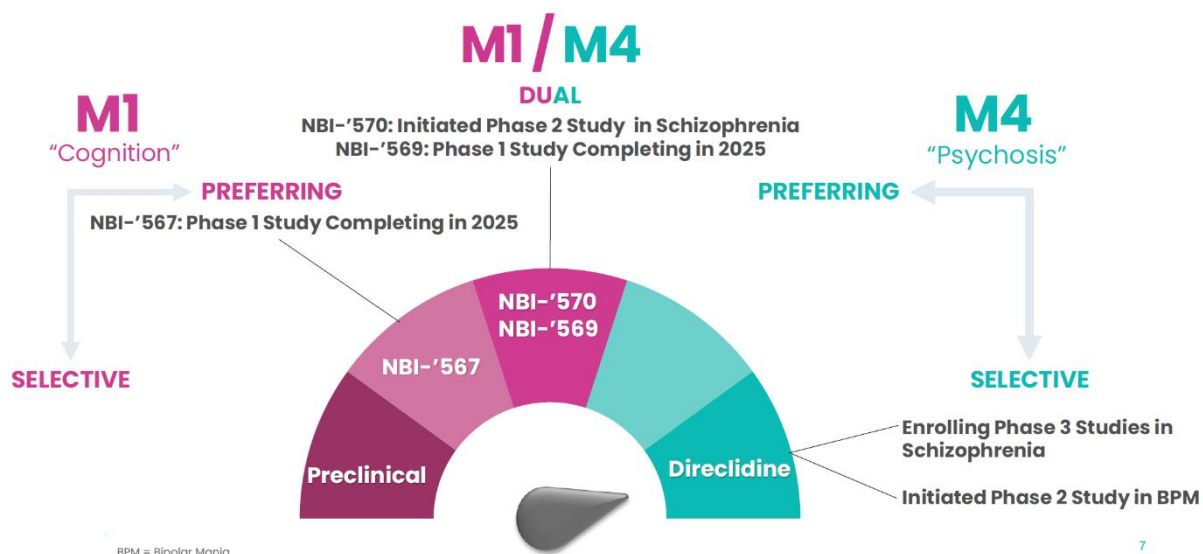
- **Launched broad new pipeline**, advancing next-gen BIC therapies for obesity and metabolic disorders
- **Convenient, scalable oral therapies** for sustained weight loss in a market dominated by peptides
- **Targeting key obesity-related co-morbidities:** Enhanced outcomes in cardiovascular, renal, and liver diseases
- **Reducing side effects and broadening out** to difficult to treat populations

MECHANISM	<b>NXera</b> 
GLP-1 ag	
GIP ant	
Amylin ag	
Multiple other targets of interest	

Nxera aims to redefine obesity, weight management and related co-morbidities by delivering potent, oral small molecules to meet a critical global need at scale



Neurocrine is advancing the world's most comprehensive portfolio of muscarinic agonists to treat neuropsychiatric disorders



Program	Mechanism	Disease State	Stage of Development
Direclidine	M4 Agonist	Schizophrenia	Phase 3
		Bipolar Mania	Phase 2
NBI-'570	Dual M1/M4 Agonist	Schizophrenia / LAI Potential	Phase 2
NBI-'569	Dual M1/M4 Agonist	Alzheimer's Psychosis	Entering Phase 1b
NBI-'567	M1 Preferring Agonist	Alzheimer's Cognition Lewy Body Dementia	Phase 1

Five clinical-stage programs spanning the M1, M4, and dual M1/M4 mechanisms designed using NxWave™



# Centessa is advancing ORX750, a potential best-in-class Orexin Receptor 2 agonist for treatment of NT1, NT2 and IH



## Potential BIC for NT1, NT2 and IH

### ORX750

### CRYSTAL-1 Phase 2a study in NT1, NT2 and IH



Evaluate safety, tolerability, and PK in NT1, NT2, and IH patients

Efficacy assessment registrational endpoints: **Maintenance of Wakefulness Test (MWT), Epworth Sleepiness Scale (ESS), weekly cataplexy rate** (NT1 patients only), and overall symptom improvement\*

Exploratory efficacy assessments will measure sleep, **cognition, attention, memory**, and general health

***First robust demonstration** of oral OX2R agonist addressing wakefulness needs of patients across NT1, NT2 and IH...*

- ✓ **Generally favorable safety and tolerability profile**
- ✓ **Statistically significant, clinically meaningful and dose-dependent efficacy**
- ✓ **Dose escalation** across ongoing and future cohorts with **once-daily and split-dose regimens**, enabled by Phase 1 data

...Expect to initiate registration program in Q1 2026

## Phase 2a study update

Endpoints	
Maintenance of Wakefulness Test (MWT)	>20 min change at 1.5mg vs baseline (with half of participants >30 min). <i>NT1</i> >10 min change at 4mg vs baseline. <i>NT2</i>
Epworth Sleepiness Scale (ESS)	1.5mg = 5.1 vs 18.7 (placebo). <i>NT1</i> 4mg = 8.1 vs 15.9 (placebo). <i>NT2</i>
Weekly Cataplexy Rate (WCR)	87% relative reduction at 1.5mg vs placebo. <i>NT1</i>
Participants	55 participants (NT1, NT2 & IH)
Next step	Registrational Program initiation planned for Q1 2026

Initial Phase 2a data mark first robust demonstration of oral OX2R agonist addressing wakefulness needs of patients across all three indications; **Expect to initiate registrational program in Q1 2026**





# FY2026 Objectives and beyond

Chris Cargill, President and CEO

05



## Priority objectives for FY2026

01

JPY 19.5 billion+ Net product sales  
(PIVLAZ<sup>®</sup> plus QUVIVIQ<sup>®</sup>)



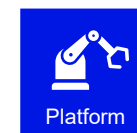
02

Get one or more late-stage assets  
for Japan and APAC (excl. China)



03

Sign one or more high-value partnership deals



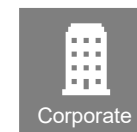
04

Initiate at least one partner-sponsored phase 2 trial



05

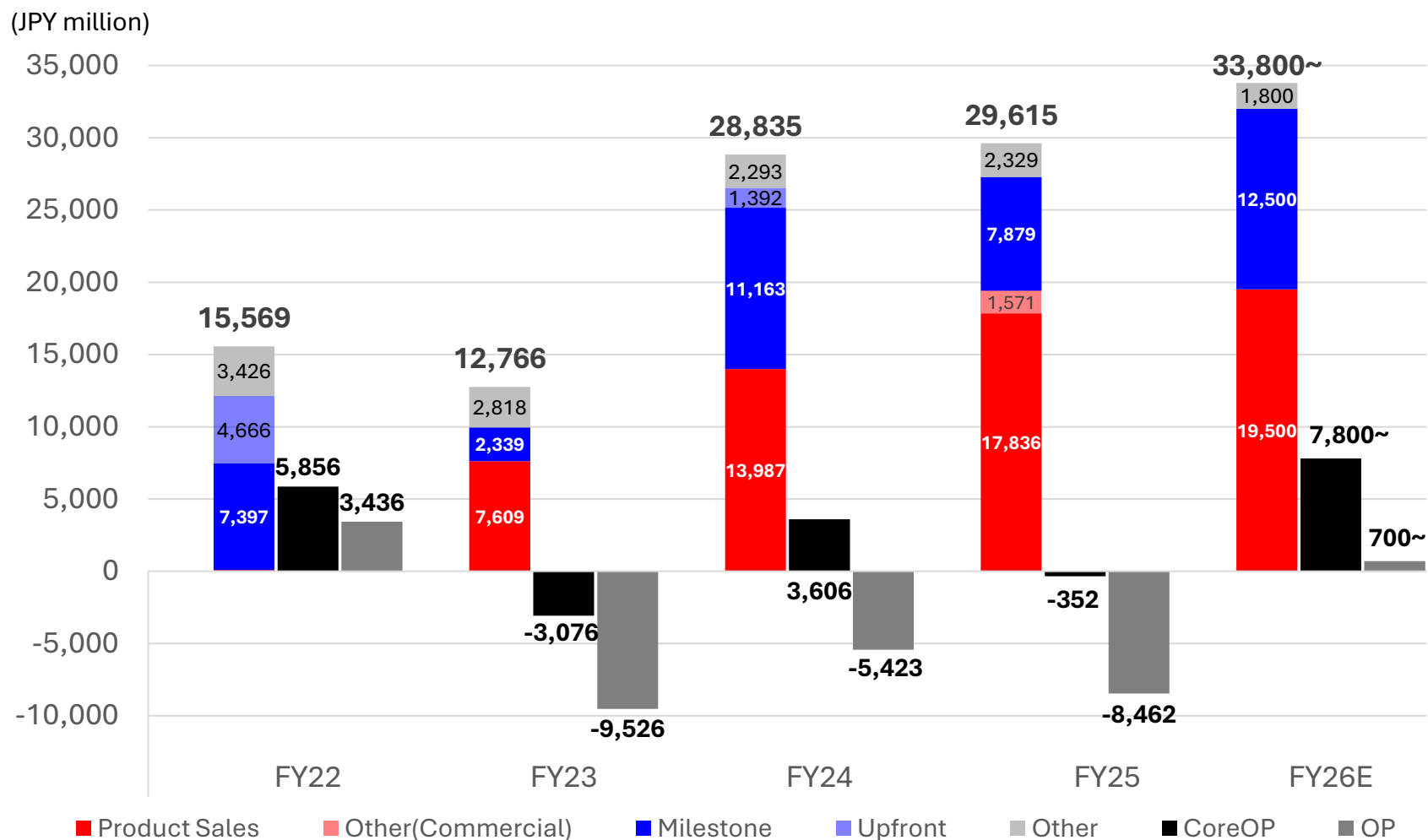
Reduce total costs by >10% and  
achieve full-year profitability on IFRS basis





# Historical financial and 2026 guidance (Without significant upfront from BD activity)

Target profitability for both Core Operating Profit and Operating Profit in FY26



## FY26 Strategy



- Multiple milestones to be received from Neurocrine, Centessa, Lilly, AbbVie, etc.
- Plan to out-license priority programs, including GPR52 agonist and EP4 agonist



- Pivlaz: +5% YoY
- Quviviq: +30% YoY





- Rationalize investment in clinical-stage assets and focus funding on obesity & metabolic programs
- Pursue margin maximization in the commercial business



# Breakdown of 2026 guidance (Without significant upfront from BD activity)

Commercial business profitability has grown significantly. Platform business has reached breakeven on a core basis

(JPY million)	 Platform* <sup>1</sup>		 Commercial* <sup>2</sup>		=	Consolidated P&L (Core)		+	Non-core costs	=	Consolidated P&L (IFRS)	
		(YoY)		(YoY)			(YoY)					(YoY)
<b>Revenue</b>	14,300	+40%	19,500	+0%		33,800	+14%		Total : 7,100		33,800	+14%
<b>Cost of Sales</b>	1,400	-34%	5,700	-5%		7,100	-13%		<b>A</b> Amortization (1,800)		7,200	-12%
<b>SG&amp;A*<sup>3</sup></b>	5,700	+15%	3,700	-32%		9,400	-10%		<b>B</b> Other (3,100)		14,200	-7%
<b>R&amp;D*<sup>3</sup></b>	8,100	-31%	2,400	+78%		10,500	-19%		<b>B</b> Other (1,500)		12,000	-17%
<b>Other income</b>	1,000	-615	-	+7		1,000	-608		(700)		300	+489
<b>OP/Core OP</b>	<b>100</b>	<b>+6,999</b>	<b>7,700</b>	<b>+18%</b>		<b>Core OP 7,800</b>	<b>+8,152</b>				<b>OP 700</b>	<b>+9,162</b>

**A** Amortization of intangible assets (currently relates to PIVLAZ® and QUVIVIQ®).

**B** 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. (ex -Nxera Pharma Basel branch)

\*2 = Nxera Pharma Japan (formerly Idorsia Pharmaceuticals Japan) + Nxera Pharma Korea (formerly Idorsia Pharmaceuticals Korea) + Nxera Pharma Basel branch

\*3 = We expect the effects of restructuring initiatives implemented since Nov 2025 to become more evident in the 2H26



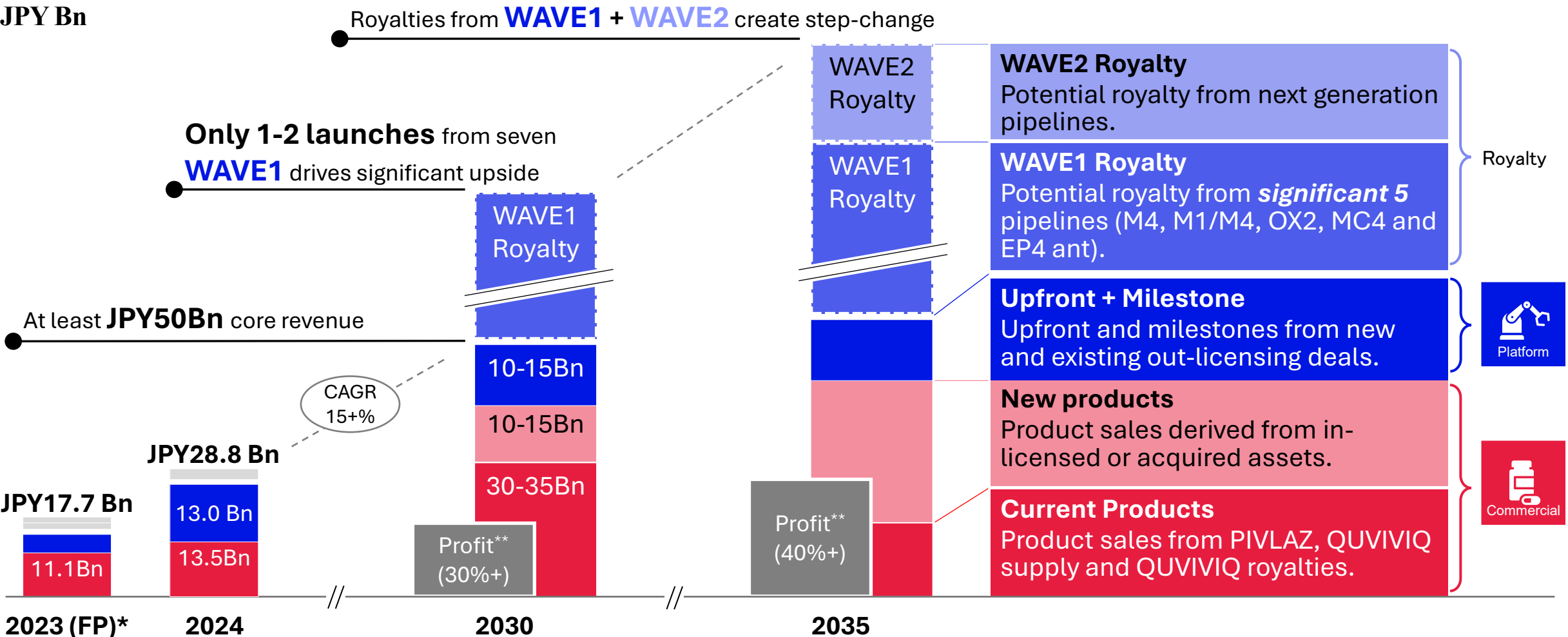
## Looking ahead to potential catalysts in 2026\*

PROGRAM	PARTNER	TIMING	EVENT	
ORX750 (OX2 agonist)		Q1 2026	Phase 2a data across NT1, NT2, and IH	
ORX750 (OX2 agonist)		Q1 2026	Registrational program start in NT1/NT2/IH	
ORX142 (OX2 agonist)		Q1 2026	Phase 2 study start	
ORX489 (OX2 agonist)		Q1 2026	Phase 1 study start	
NBI'570 (M1/M4 ago)		Q1 2026	Phase 2 study start	
Multiple discovery collaboration progress		1H 2026	Progression through discovery stage	
Cenerimod		Q4 2026	Phase 3 data readout	
NBI'567 (M1 ago) / NBI'569 (M1/M4 ago)		2H 2026	Clinical progression	
PF'669 (MC4 antagonist)		2026	Phase 1 data readout	
NBI'567 (M1 ago) / NBI'569 (M1/M4 ago) / NBI'570 (M1/M4 ago)		2026	Phase 1 data disclosure	
New global out-licenses		Anytime	Out licensing and/or discovery collabs	
New Japan / APAC in-licenses		Anytime	Acquire/in-license late-stage medicines	
QUVIVIQ™ / Vamorolone		Anytime	APAC out-licensing deals	

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



# 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.





# Questions?



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# Thank you



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