

Nxera Pharma

Q2 FY2025 Financial Results

8 August 2025 | Nxera Pharma Co., Ltd. (TSE: 4565)

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Agenda

- 01 Operational Highlights
- 02 Financial Results
- 03 Japan /APAC Commercial Business
- 04 R&D Progress
- 05 FY2025 Objectives and Beyond
- 06 Appendix



Operational Highlights

Chris Cargill, President and CEO

01



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)



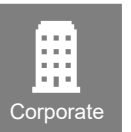
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Execute at least one new major partnership, and initiate at least one new in-house Ph.2 study



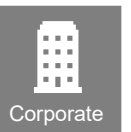
04

Investment in systems and applications for efficiency and scalability



05

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





Advancing as a global biopharma with strong foundations

CORPORATE MILESTONES

- ✓ Enriched the management structure with appointments of two new external directors
- ✓ Enhancing information provision activities with the appointment of new IR head
- ✓ NPJ's representative directorship changed from two to one.

UK R&D

- ✓ TMP-301 entered Ph2 study (mGlu5 NAM)
- ✓ NBI-568 entered Ph3 study (M4 agonist)
- ✓ ORX142 entered Ph1 study (OX2 agonist)
- ✓ 7 new proprietary obesity programs announced
- ✓ PF'522 completed Ph1 study (GLP-1 agonist), Pfizer portfolio decision to discontinue development

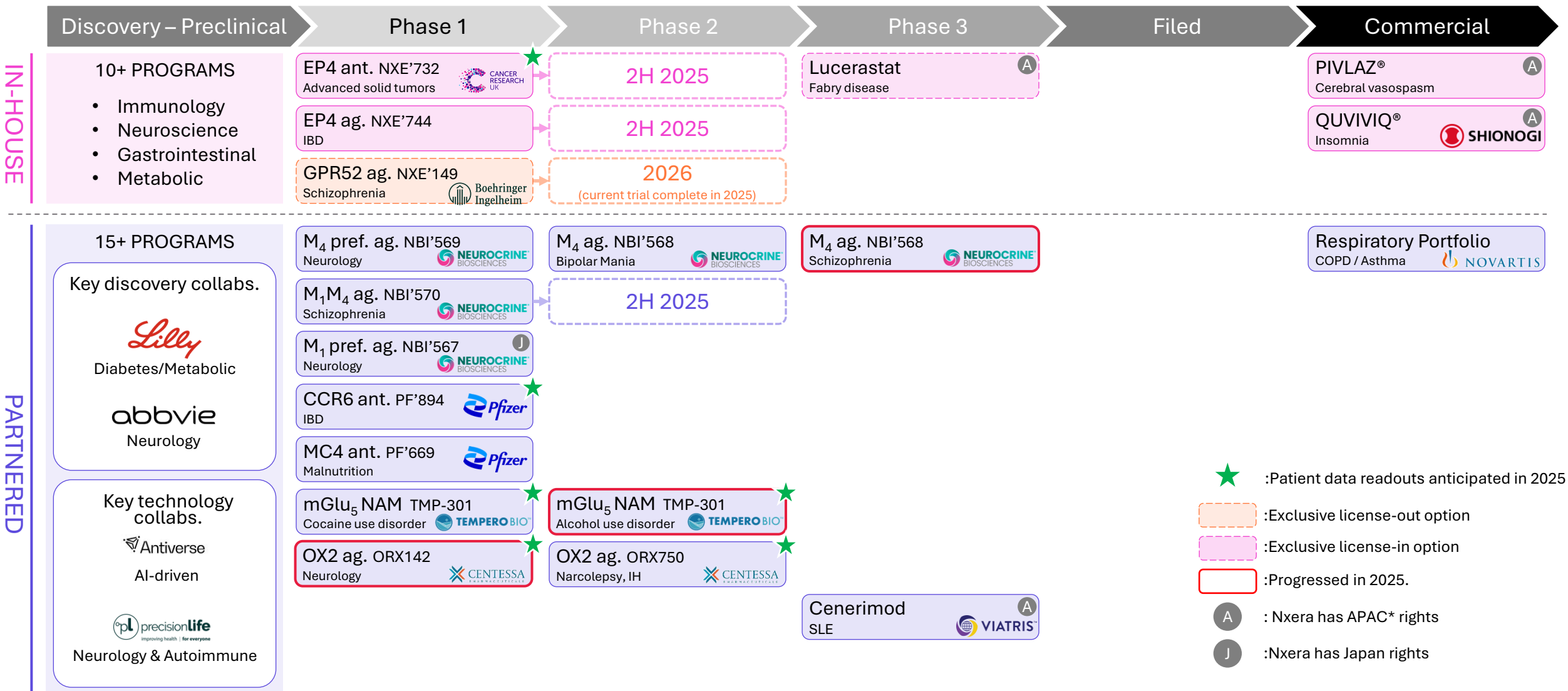
JAPAN/APAC BUSINESS

- ✓ PIVLAZ[®] established strong position in Japan
- ✓ Entered a new agreement for Daridorexant in Taiwan (Scheduled for launch in mid-26)
- ✓ Assigned rights for Cenerimod in Japan and APAC to Viatrix
- ✓ PIVLAZ[®]'s exploring possibilities for free medical care in Korea (withdrawal from drug price negotiations).

Accelerating science, expanding capabilities and delivering impact



Major pipeline Overview (incl. projections)



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






*NXE0039732 (EP4 antagonist) is categorized as an in-house asset as we have not licensed out. Under the Clinical Trial and Licence Agreement (CTLA) in 2022, Cancer Research UK sponsors, designs and executes a Phase I/IIa clinical trial of NXE0039732, and Nxera holds a licence to the results generated under the trial to continue the clinical development and commercialization of NXE0039732.



Nxera launched broad new pipeline for obesity and chronic weight management

7 programs underway with in-house development in the obesity area

Aligned with the Oral Therapeutics Shift

MECHANISM	ORAL SMALL MOLECULE*	
GLP-1 ag	21	
GIP ag/ant	1	
Amylin ag	1	
Apelin ag	0	
Other	1	(Not disclosed)

Highlights

- Benefits of oral small molecules for metabolic diseases:
 - ✓ Enables polypharmacology
 - ✓ Greater patient convenience
 - ✓ Improved access in primary care and emerging markets
 - ✓ No requirement for cold chain distribution and storage
 - ✓ Reduced Cost of Goods and ease manufacturing scalability
 - ✓ Positive payor story
- Nxera advancing multiple programs targeting GLP-1, GIP, Amylin and Apelin receptors. Partnership negotiations in this therapeutic area also ongoing
- Strong progress with our partner Eli Lilly, worth up to ~US\$700m, with key program milestone achieved earlier this year



Financial Results

Hironoshin Nomura, CFO

02

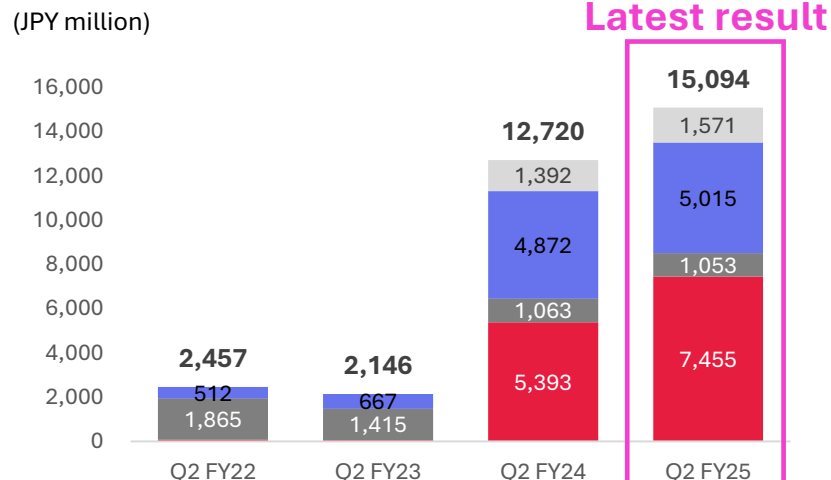


Key financial indicators

H1 Revenue up 19% driven by Product Sales and Milestones (due to progress of partnered programs).

Major factors

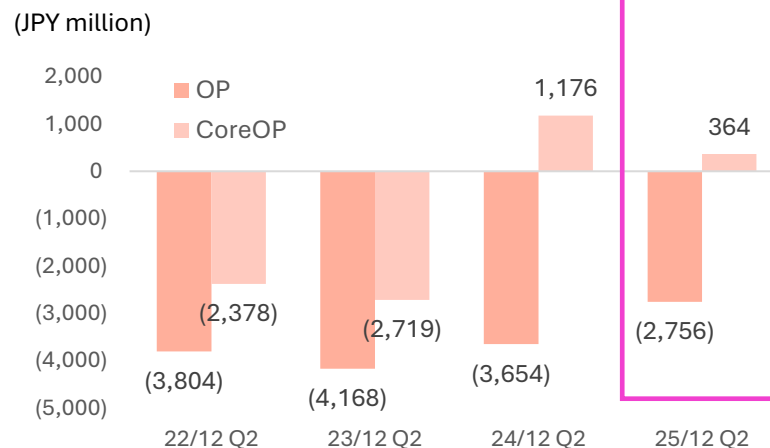
Revenue



Upfront¹ Milestone² Royalty / Other Product Sales

- USD10m received from Viatris for assignment of rights for Cenerimod in Japan and APAC (February 2025).
- Partner Neurocrine started a Ph3 trial of NBI-1117568 in schizophrenia triggering a US\$15 million milestone.
- Partner Centessa started a Ph1 trial of orexin receptor agonist ORX142 triggering US\$4.8 million in milestones.
- Royalties from respiratory portfolio sales by Novartis were broadly flat.
- 8% growth in PIVLAZ® sales (to JPY5,805m).
- Inclusion of QUVIVIQ® supply & royalty income in H1 25.

Operating Profit / (Loss)



R&D Cost of Sales G&A

- Increased investment in R&D activities, including 3 programs in clinical trials.
- Increase due to inclusion of QUVIVIQ® product supply costs.
- Non-cash PIVLAZ® inventory charge no longer required.
- Decrease in NPJ costs due to targeted savings.
- Inclusion of QUVIVIQ® intangible asset amortization in H1 25.

¹ Upfront fee revenue recognised at deal inception

² Milestone revenue recognised at milestone event + deferred revenue releases

Business is progressing well, with significant growth in commercial revenues

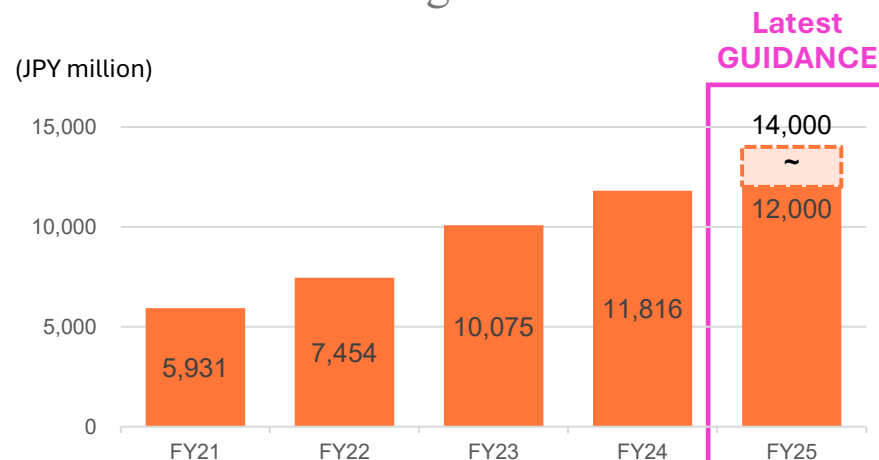
- A** Amortization of intangible assets (currently relates to PIVLAZ® and QUVIVIQ®).
- B** Amortization of other intangible assets (e.g. IP), depreciation (e.g. laboratory equipment), share-based payments and other restructuring costs.

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



Full year cost Guidance for FY2025 (Unchanged)

Small increase in R&D expenditure with progression of several 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

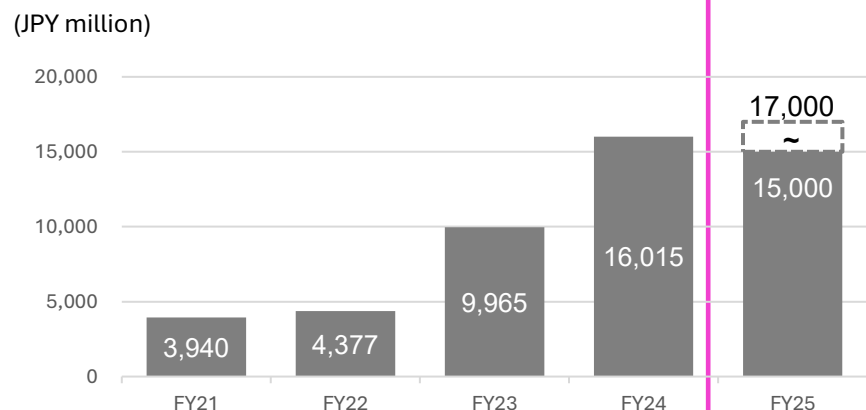


R&D expenses (IFRS basis)

JPY12,000 to JPY14,000m (No change)

Key points in FY2025

- The guidance remains unchanged as R&D expenditure will reduce in the second half.
- 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 (No change)

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.

The background features a blurred image of a globe with blue and green hues, suggesting a global or international theme. In the top left corner, there is a glass containing a red liquid, likely wine. On the right side, a dark, curved object, possibly a glass or a piece of jewelry, is visible. The overall aesthetic is professional and sophisticated.

Japan/APAC Commercial Business

Hironoshin Nomura, CFO

03

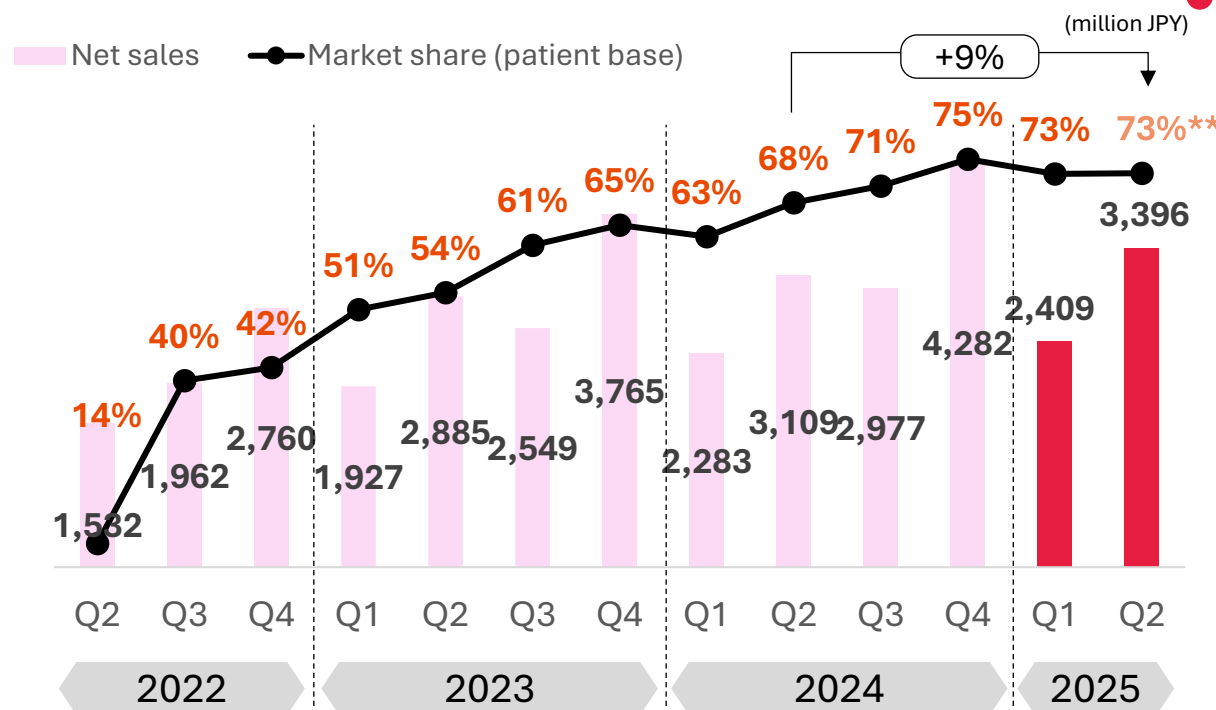


PIVLAZ® (clazosentan, an endothelin A antagonist)

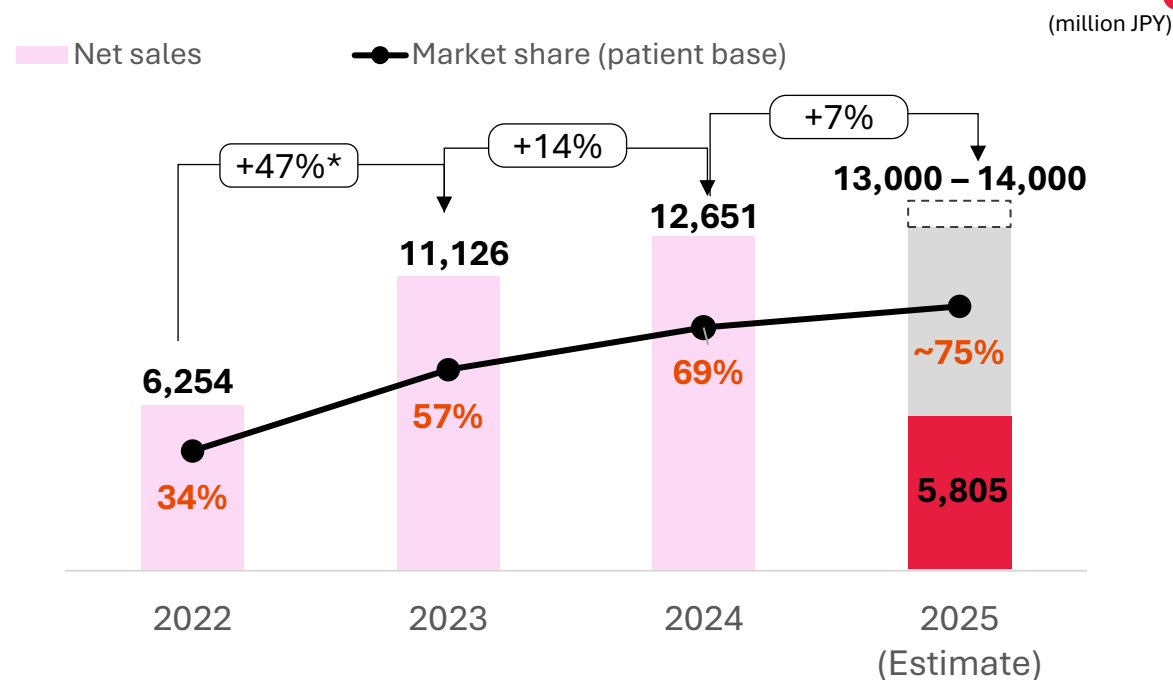
Our first commercially available product for the prevention of cerebral vasospasm in patients with Aneurysmal Subarachnoid Haemorrhage (aSAH)



Quarterly PIVLAZ® Net Sales



Annual PIVLAZ® sales and its growth



Steady progress against company expectations

Source: MDV DPC hospital data

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

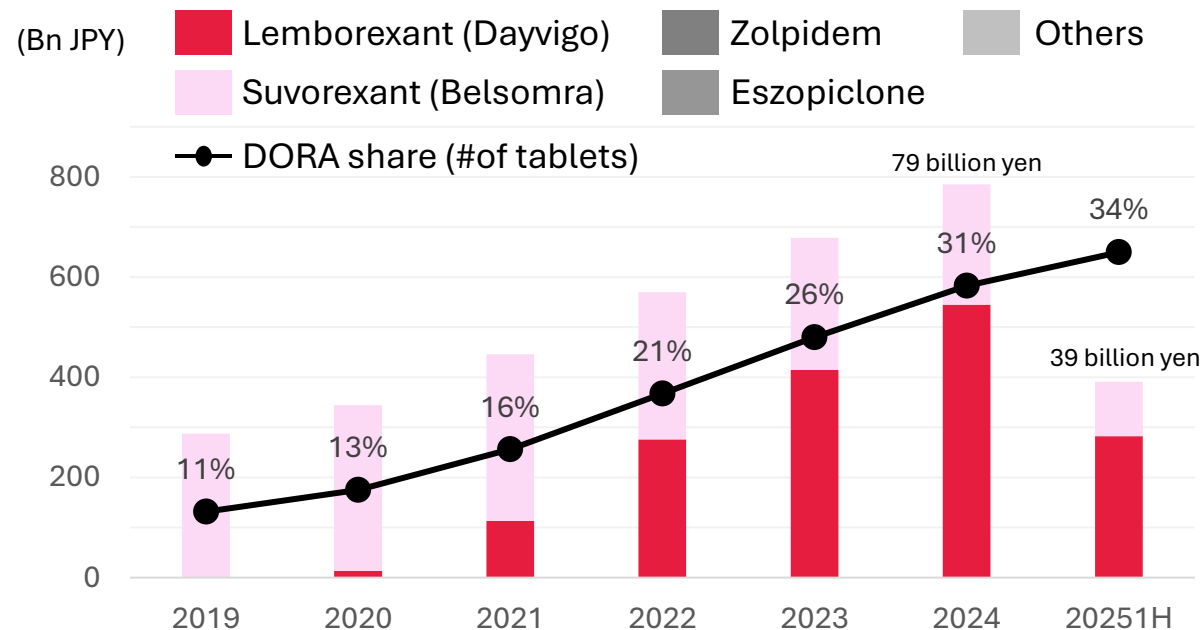


QUVIVIQ® (daridorexant, dual orexin antagonist “DORA”)

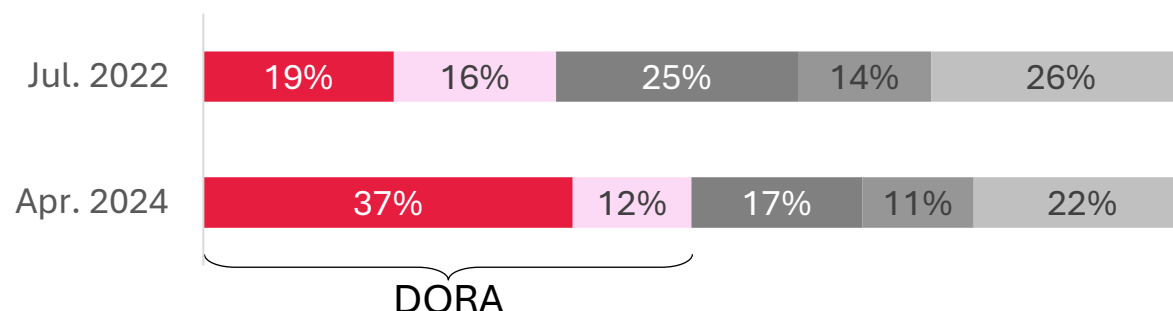
DORA is rapidly establishing its position in the treatment paradigm for insomnia



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

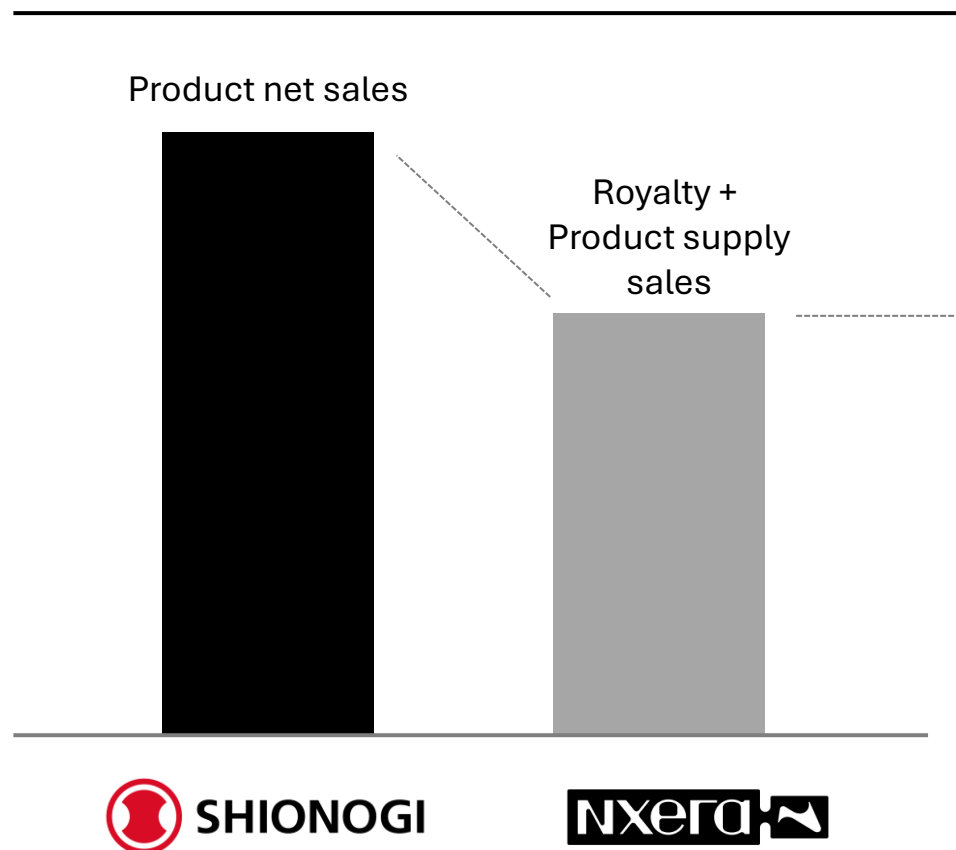


QUVIVIQ® Business structure

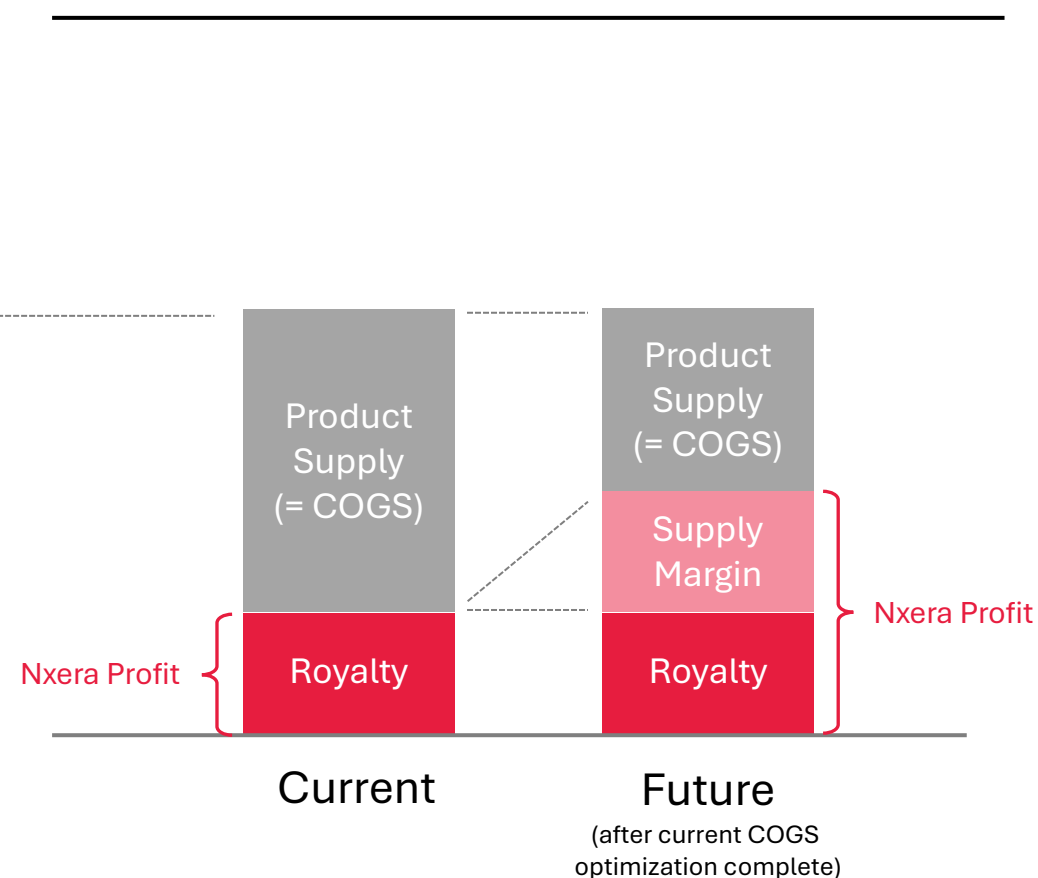
Royalty profits initiated and supply margin expected in a few years



Sales structure



Profit structure for Nxera





Full year product sales guidance

Target 13.0 - 14.0 Bn JPY (PIVLAZ[®]) from net sales, and 4.0 - 5.0 Bn JPY (QUVIVIQ[®]) from royalty and supply



Target sales
in FY2025



13.0 – 14.0 Bn JPY

(NHI Sales: 15.7 – 16.9 Bn JPY)

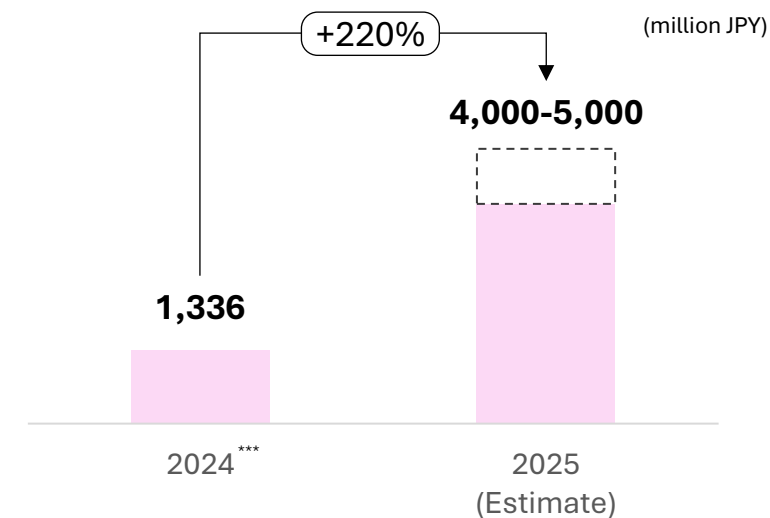
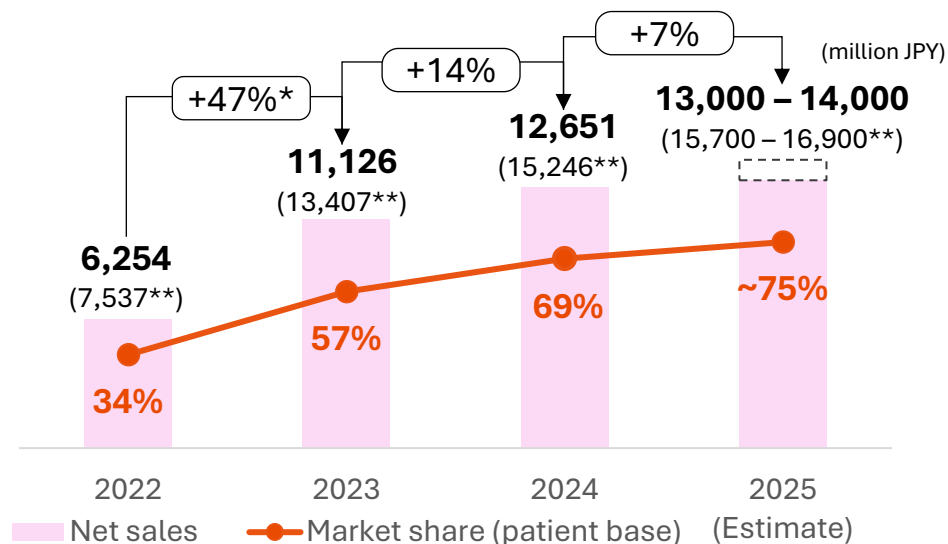
+7%

4.0 – 5.0 Bn JPY

(Shionogi: FY26/3E = 9.3 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

CSO and President of Nxera Pharma UK
Matt Barnes

04



Key Events 1H 2025

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

DISCOVERY



Launch of 7 new proprietary obesity programs announced

Aug '25

[PR LINK](#)



\$ Undisclosed development milestone payment achieved under multi-target collaboration targeting diabetes and metabolic diseases

Jun '25

[PR LINK](#)

PHASE 1



\$4.8M milestone payment received for initiation of clinical development of ORX142, the second novel OX2R agonist progressing into clinical trials from this partnership

Jul '25

[PR LINK](#)



NXE-732 is a selective EP4 antagonist, P1 dose escalation study completed. Ph1 clinical data to be disclosed at ESMO (Oct 2025).



NXE-744 is a first-in-class EP4 agonist. P1 studies, including single- and multiple-ascending dose cohorts, have now completed with no concerning safety signals to date.



NXE-149 is a first-in-class GPR52 agonist, P1b proof-of-mechanism study remains ongoing. This study is expected to complete in the second half of 2025.

PHASE 2



Tempero Bio initiates Phase 2 trial with TMP-301 for Alcohol Use Disorder. TMP-301 is a potent, selective, orally available mGluR5 NAM identified and designed using the NxWave™ Platform

Mar '25

[PR LINK](#)



Neurocrine present new positive Phase 2 study data for NBI-568 at American Society of Clinical Psychopharmacology

May '25

[PR LINK](#)

PHASE 3



\$15M milestone payment following dosing of first patient in Phase 3 trial of NBI-568 as a potential treatment for schizophrenia. (Clinical Trial ID: NCT06963034)

Jun '25

[PR LINK](#)



To be presented today

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



NxWave™: Proprietary structure-based drug design delivering proven pipeline impact



Target ID and Validation

Identifying the best targets



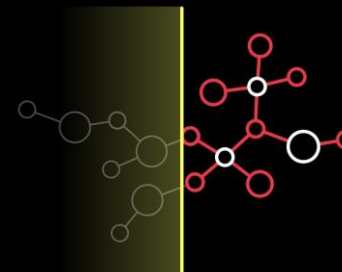
NxStaR™

Stabilising the right targets



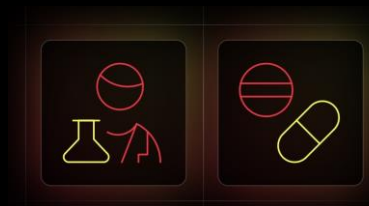
NxHit™

Identifying the optimal hits



NxDesign™

Selecting the best candidate



Translational Med.

Testing the therapeutic hypothesis

World-leading productivity

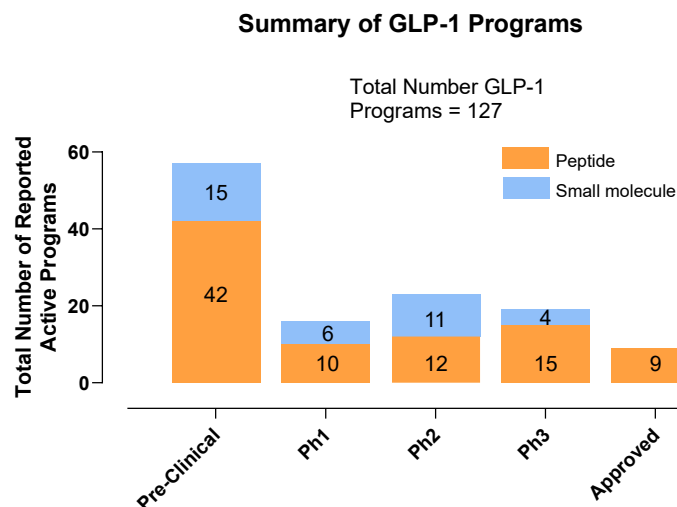
	Clinical Candidates		Phase 1	Phase 2	Phase 3
Total		29	18	5	1
Active (as of August 2025)	✓	15	✓ 11	✓ 4	✓ 1



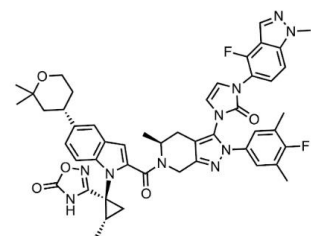
Significant opportunity to expand beyond peptides leveraging our proprietary NxWave™

Anchored by differentiated positions on a novel GLP-1R agonist with an additional 6 innovative programs

Opportunity for small molecules



Two main small molecule chemotypes

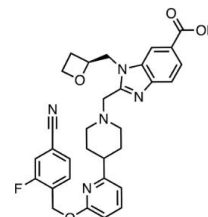


orforglipron
GLP-1R
oral non-peptide GLP-1R partial agonist
Ph. III for obesity + T2D
from LLC-PK1 cell HTS + opt
CHUGAI, SHIZUOKA, JP; ELI LILLY, INDIANAPOLIS, IN

- Synthetic complexity
- COG risk

Patent landscape dominated by two chemotypes:

~20% Orfor-like

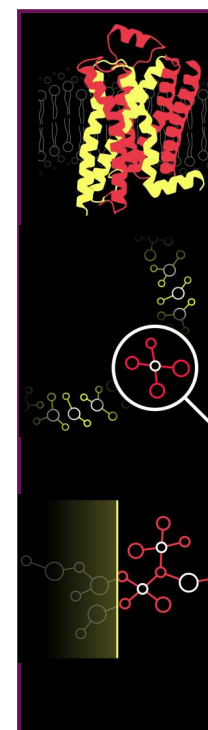


danuglipron
GLP-1R
oral non-peptide GLP-1R full agonist
Ph. IIb for obesity + Ph. II for T2D
from sensitized cell HTS of 2.8M cmpds + opt
PFIZER, CAMBRIDGE, MA

- Safety Flags
- DILI risk

~80% Danu-like

Nxera differentiated approach



NxStaR™

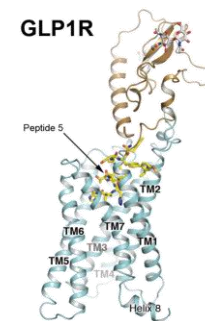
- ✓ Stabilised proteins for DNA encoded library screen (DEL)

NxHit™

- ✓ Proprietary small molecule libraries

NxDesign™

- ✓ First to solve GLP-1R bound to a peptide agonist



NxWave™ Structure Based Drug Design: Precision chemistry. Proven engine. Next-Gen metabolic drugs



Preclinical metabolic assets: A strategic focus for investment and pipeline expansion

Recent transactions highlight the demand for oral metabolic therapeutics with differentiation potential

GLP-1 small molecules attracting billion-dollar deals

Acquiring Company	Originating Company	Asset (preclinical)	Date	Upfront	Total Deal Size
Madrigal Pharma	CSPC Pharma	GLP1 SME	Jul '25	\$120M	Up to \$2Bn
Novo	Septerna	Multiple including GLP1 SME	May '25	\$200M	Up to \$2.2Bn
Merck	Hansoh Pharma	GLP1 SME	Dec '24	\$112M	Up to \$1.9Bn

Select GLP-1 small molecule transactions (past 8 months)

Oral delivery broadens metabolic impact

- ✓ **Long-term weight maintenance:** Convenient, scalable oral therapies for sustained weight loss.
- ✓ **Targeting key obesity-related co-morbidities:** Enhanced outcomes in cardiovascular, renal, and liver diseases
- ✓ **Reducing side effects and broadening out to at risk populations:** Targeted treatments for elderly, post-menopausal, and sarcopenic populations
- ✓ **Combination approaches:** require chemistry flexibility

The next wave of obesity treatments will be oral, safe and scalable – and we are ready to lead it



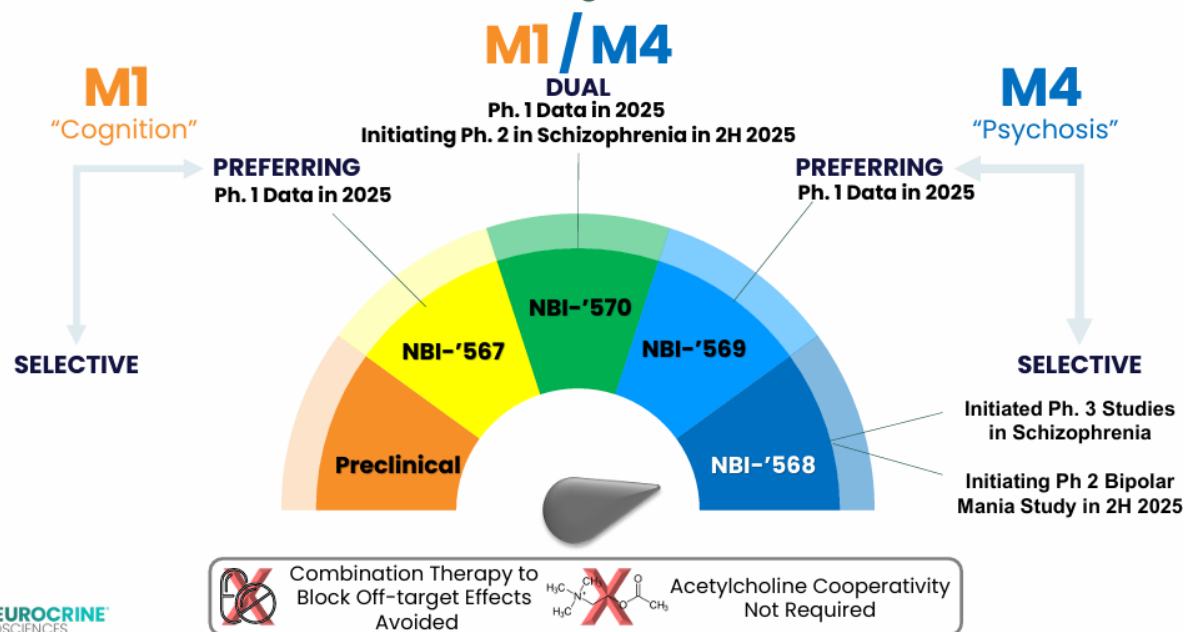
Neurocrine is advancing a broad muscarinic agonist pipeline

Five Clinical-Stage Programs Spanning M1, M4, and Dual M1/M4 Mechanisms with Readouts Expected in 2025



Muscarinic Platform Includes Multiple Clinical Programs

From M1 to M4 Selective Orthosteric Agonists



Compounds	Target	Indication	Phase1	Phase2	Phase3
NBI'568	M4 agonist	Schizophrenia			2025~
NBI'568	M4 agonist	Bipolar disorder		2025 2H~	
NBI'570	M1/4 agonist	Schizophrenia		2025 2H~	
NBI'569	M4 agonist	-			P1 results to be reported in 2025
NBI'567	M1 agonist	-			

Designed using NxWave™ - Selective Orthosteric Agonists Targeting Schizophrenia, Bipolar Disorder, and Beyond



NBI-568 Phase 3 underway – a new modality for schizophrenia treatment

Advancing the first and only selective M4 orthosteric agonist into phase 3

NBI-568 Short-Term Study Design

Simple Trial Design Testing 20mg QD vs. Placebo with 1:1 Randomization
Phase 3 Program Initiated in April 2025 with 2nd Phase 3 Program Initiating in Q3 2025



Notes:

Adults with PANSS ≥85,
Ages 18-65 (inpatient)

Primary Endpoint: Change in PANSS
total score from baseline at Week 5

Subjects randomized to placebo or NBI-568 20 mg QD during
the 5-week double-blind treatment period (1:1 randomization)

Differentiation points

Type of Muscarinic Activation	Subtype Selectivity	Requires Endogenous Ligand (Acetylcholine)
Pan Agonism	Low Targets M1-M5	No
Positive Allosteric Modulation	High Targets only M4	Yes
Selective Agonism (NBI-568)	High Targets only M4 >500-Fold Agonist Selectivity for M4 Receptor Over Other Muscarinic Receptors	No

Large opportunity for NBI-568 – a novel and differentiated asset



With No Reliance on Innate Acetylcholine Levels, NBI-568 is the **First and Only Highly Selective Orthosteric M4 Agonist**, Potentially Introducing a **New Modality for Treatment**



Convenience of **Once-daily Dosing with or without Food**



NBI-568 Potentially Offers a Compelling and Competitive Benefit-Risk profile



Increased Conviction in **Indication Expansion Opportunities** for NBI-568 and Neurocrine's Broad Muscarinic Portfolio

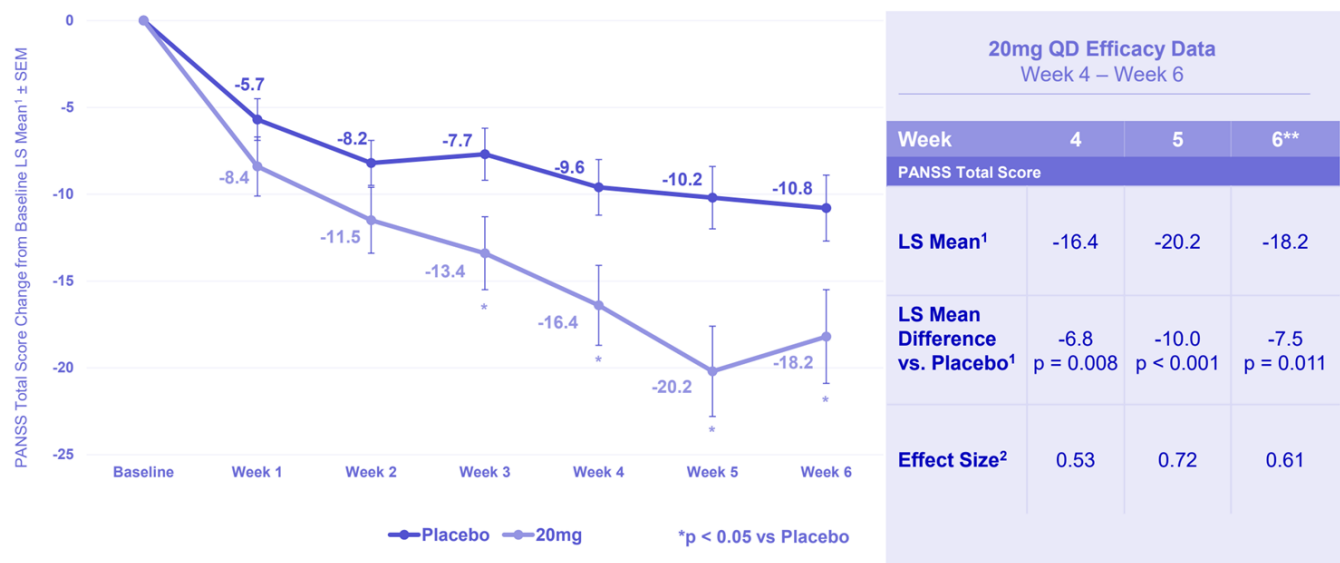
Unlocking therapeutic potential with selective orthosteric activation



Topline Results for Phase 2 Trial of NBI-568

Efficacy confirmed at 20 mg. Statistically significant difference in both PANSS and CGI-S compared to placebo.

Once-Daily 20mg Dose Demonstrated Clinically Meaningful and Statistically Significant Efficacy at Week 3, 4, 5, and 6

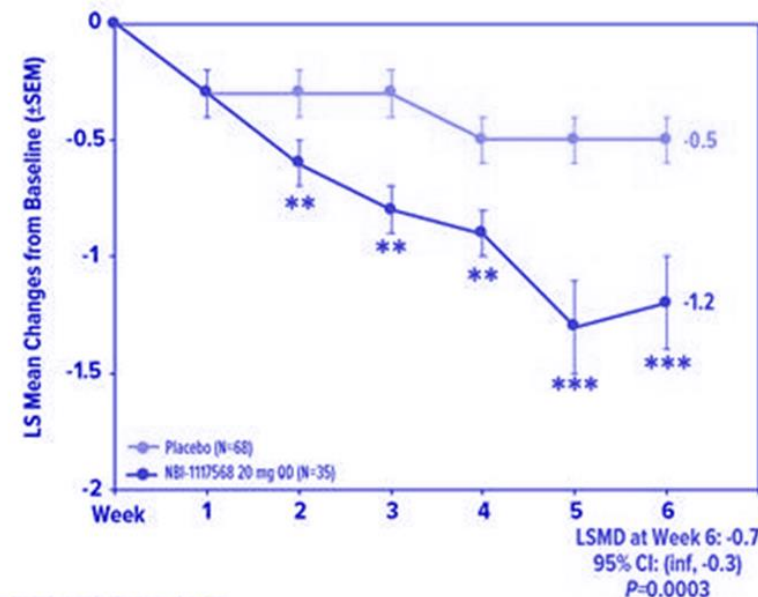


¹ Least-squares (LS) means are from a MMRM which includes treatment group, visit, and study period as fixed effects; treatment group-by-visit interaction; baseline PANSS total score as a covariate; and subject as a random effect.

² Effect size (Cohen's D) is based on observed data.

9

B. Changes in CGI-S Score



*P<0.05 **P<0.01 ***P<0.001

LS means are from a MMRM, which includes treatment group, visit, and stage of randomization as fixed effects; treatment group-by-visit interaction; baseline score as covariate; and participant as a random effect. Cohen's d based on observed values.

“The effects with the 20-milligram dose, both PANSS and CGI-S scores consistently showed statistically significant differences vs. placebo, meaning that you are seeing a reproducible response here.”



Safety: Adverse Events Risk

The gastrointestinal and cardiovascular adverse events were higher than placebo in Cobenfy, but not with NBI-568

NBI-568

	Placebo N=70	20mg QD N=40	40mg QD N=39	60mg QD N=34	30mg BID N=27	All Treated N=140
Somnolence	2 (2.9)	5 (12.5)	2 (5.1)	7 (20.6)	1 (3.7)	15 (10.7)
Dizziness	1 (1.4)	5 (12.5)	3 (7.7)	4 (11.8)	1 (3.7)	13 (9.3)
Headache	14 (20.0)	1 (2.5)	5 (12.8)	1 (2.9)	5 (18.5)	12 (8.6)
★Nausea	2 (2.9)	2 (5.0)	3 (7.7)	3 (8.8)	0	8 (5.7)
★Constipation	2 (2.9)	2 (5.0)	3 (7.7)	1 (2.9)	1 (3.7)	7 (5.0)



Cobenfy

Table 3.6. Pooled Treatment-Related Adverse Events in EMERGENT trials²⁰

Adverse Event, %	KarXT (n= 340)	Placebo (n= 343)
★Nausea	17.1%	3.2%
★Constipation	15.0%	5.2%
★Dyspepsia	12.1%	2.3%
★Vomiting	10.9%	0.9%
★Hypertension	5.9%	1.2%
Dry Mouth	5.0%	1.5%
Tachycardia	4.7%	2.0%

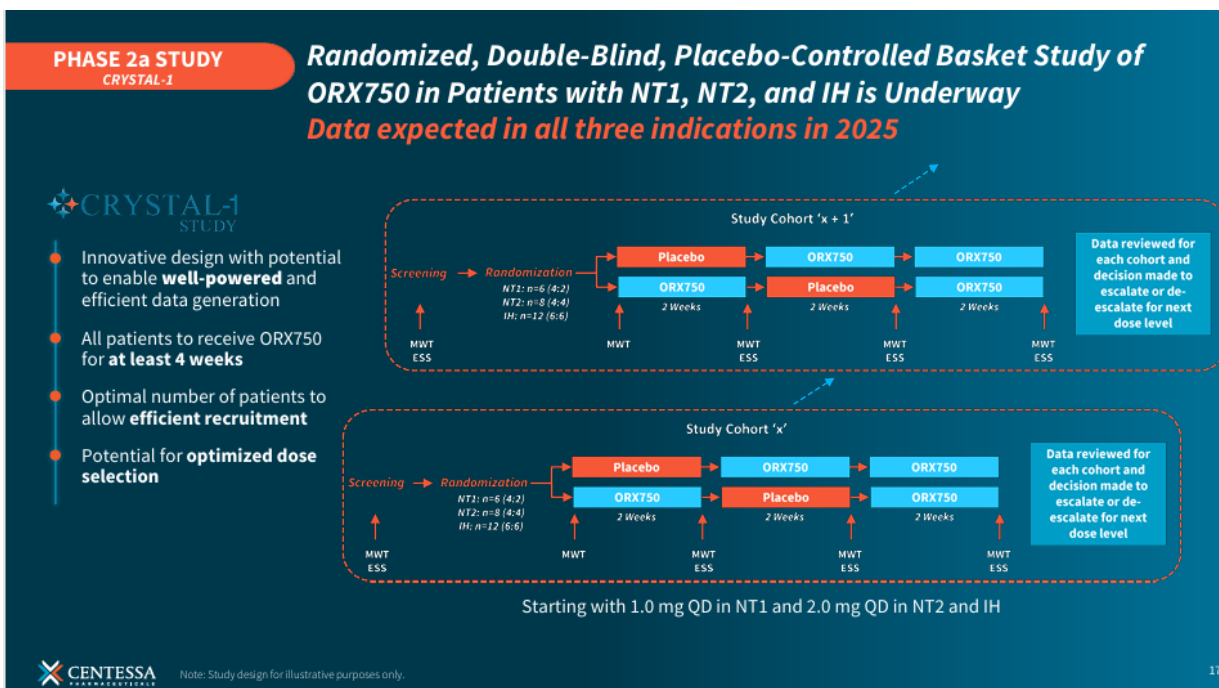


Safety			Dietary Restriction	Number of doses
Gastrointestinal (M2)	Cardiovascular (M3)	Others		
★ Similar to placebo	 Similar to placebo	Somnolence Dizziness	Nothing	Once a day
★ x3-5 vs. placebo (Four items with 10% or more)	★ x4 vs. placebo (Occurred in 5.9%)	Dry mouth	Yes (1 hour before or 2 hours after a meal)	Twice a day (co- administered with trospium chloride)



Centessa are building a leading portfolio of OX2R agonists in sleep/neuro disorders

ORX750, ORX142, and ORX489 positioned as potential first/best-in-class across NT1, NT2, IH, and neuro disorders



Positioned to be Potential Best-in-Class / First-in-Class in Emerging Category of OX2R Agonist Therapeutics

- ORX750** for the treatment of **NT1, NT2 and IH**
- ORX142** for the treatment of **neurological and neurodegenerative disorders**
- ORX489** for the treatment of **neuropsychiatric disorders**
- Earlier stage OX2R agonists and therapeutics for additional potential indications

Molecule	hOX2R EC50 (nM)	Selectivity vs. hOX1R
Native ligand orexin-A (OXA) ¹	0.035	n/a
ORX750 ¹	0.110	9,800x
ORX142 ²	0.069	13,000x
ORX489 ³	0.035	8,800x



Fluorescent imaging plate reader (FLIPR) assay with Chinese hamster ovary (CHO) cells stably expressing human recombinant OX1R or OX2R.
1. Black et al., World Sleep 2023 Abstract. 2. Black et al., European Sleep Research Society 2024 Abstract. 3. Company data / presentations.

8

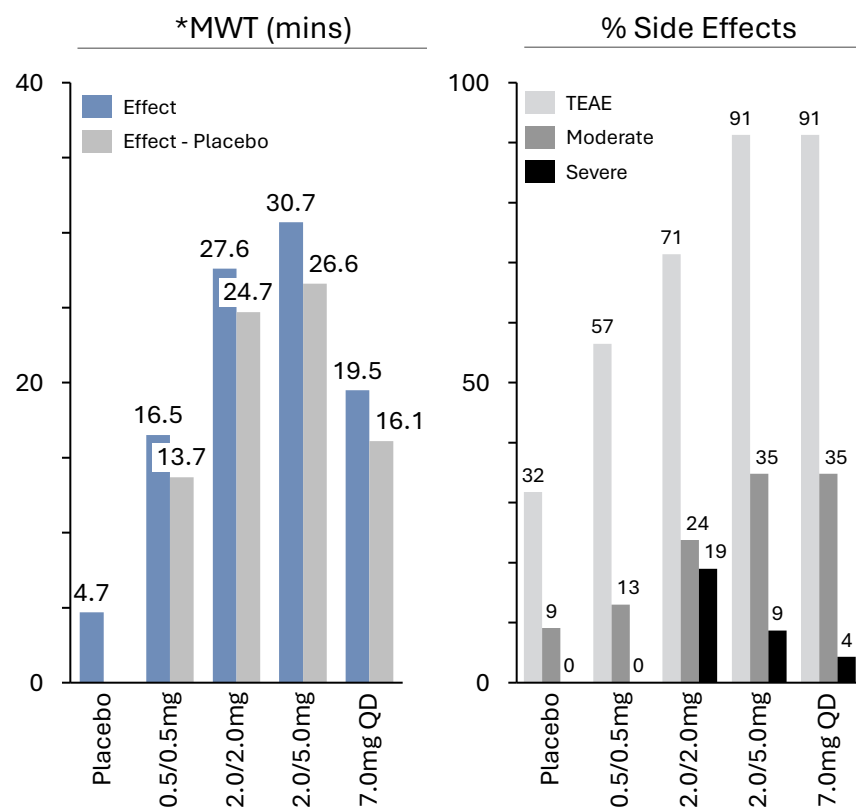
Multi-asset pipeline discovered using NxWave™ - Unlocking commercial potential across differentiated CNS indications



Data on OX2 agonist competitors

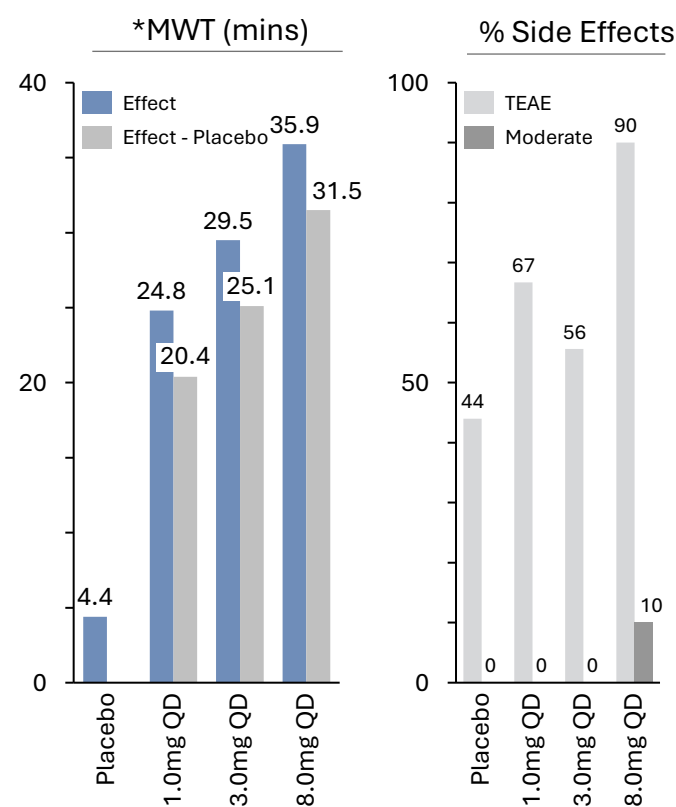
ORX750 reported favorable safety and efficacy results in Phase 1b trials

TAK-861



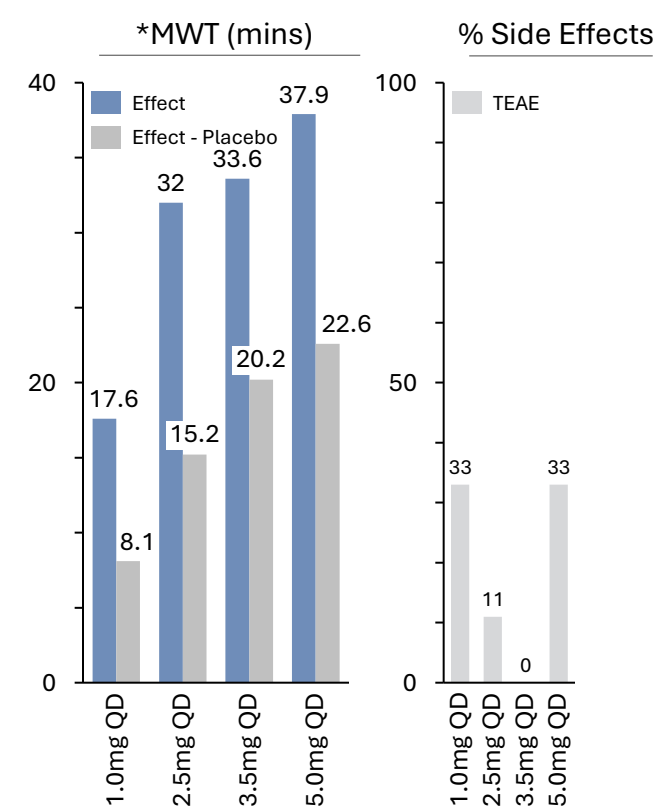
- Ph2b NT1 patients
- n=112 (Week8)

ALKS2680



- Ph1b NT1 patients
- n=34

ORX750



- Ph1b healthy volunteers
- n=10

*MWT = Maintenance of Wakefulness Test

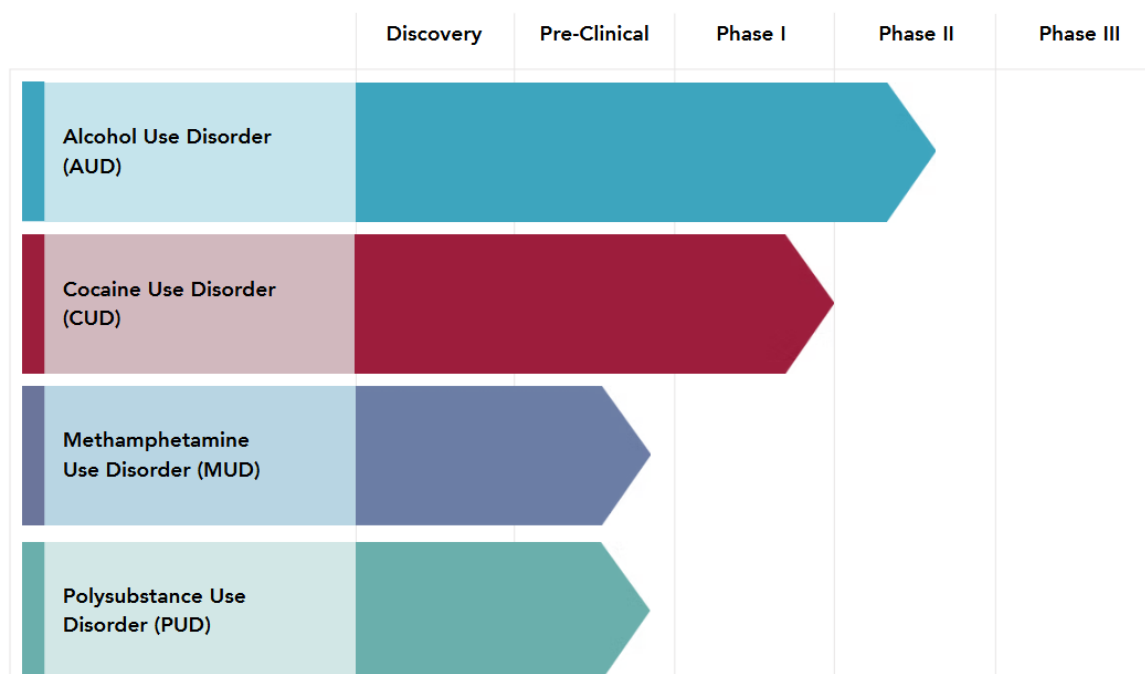
Source: Created by Nxera based on N Engl J Med 2025;392:1905-1916 and Alkermes presentation



TMP-301, an mGlu5 NAM being developed by TemperoBio

Two clinical trials in alcoholism and cocaine disorder are ongoing in patients

Pipeline







Highlights

- Tempero Bio Secures \$70 Million Series B Financing to Advance TMP-301 into Phase 2 Trials for Substance Use Disorders (March 24, 2025)
- Phase 2 for alcohol use disorder and Phase 1 for cocaine use disorder will finish in 2H 2025.
- Tempero Bio plans to initiate Phase 2 trial for cocaine use disorder within the next year

First phase 2 POC in AUD reported before year end



Internal assets progressing through early clinical development

	OPTION TO LICENSE WITH 	DISCOVERED BY 	DISCOVERED BY 	DISCOVERED BY 
Compound & Stage	NXE-149 (Ph 1b)	NXE-732 (Ph 1)	NXE-744 (Ph 1b)	
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

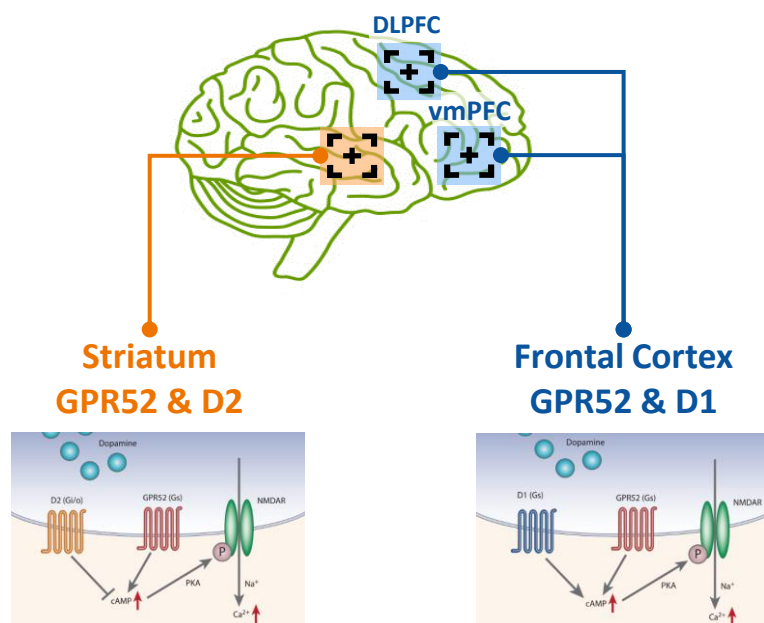


GPR52 agonist for schizophrenia

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

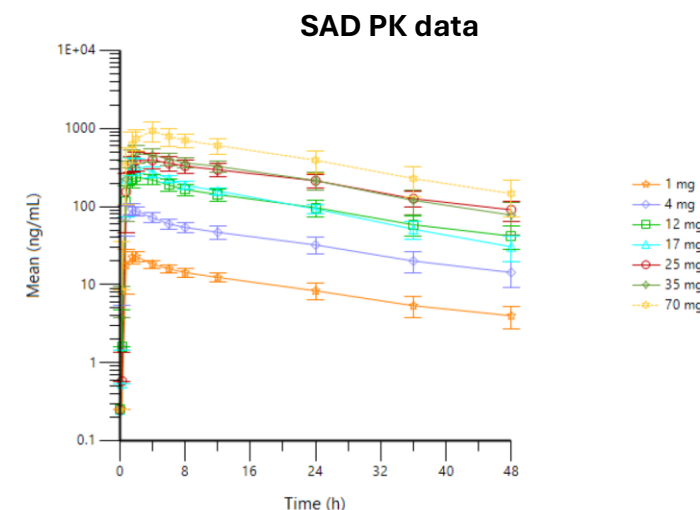
Disease Rationale

- 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



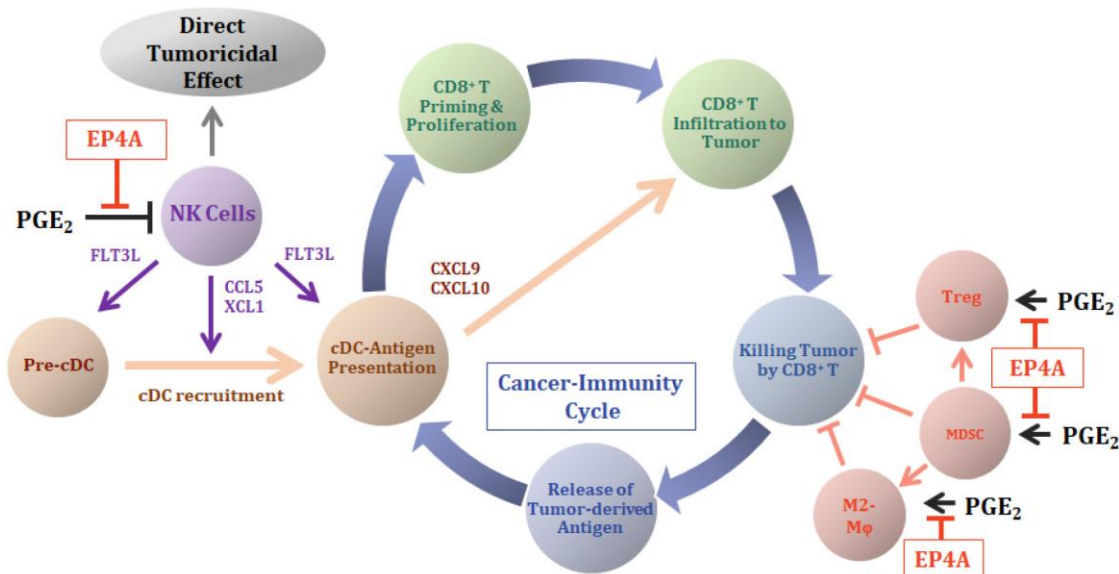


EP4 antagonism for advanced solid tumours

Alone or in combination with Checkpoint Inhibitors (CPIs)

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 enrolment completed**
 - Dose escalations with monotherapy and combination with anti-PD-L1: enrolment complete and Recommended Ph2 Dose confirmed
 - Study will continue while patients receive benefit
- Robust Ph1 interim data to date**
 - AEs have been generally mild (grade 1-2) and have resolved without dose interruption.
 - PK profile was in line with predictions and exhibits general dose proportionality across all dose levels tested.
 - Target engagement was observed at all dose levels tested and additional PD analysis, including evaluation of paired biopsies for T cell infiltration, is underway.
- Ph1 clinical data to be disclosed at ESMO (Oct 2025)**
- Ph2 recruitment ongoing in the UK, focusing on 4 specific tumour types, in combination with PD-L1**



EP4 agonist for inflammatory bowel disease (IBD)

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

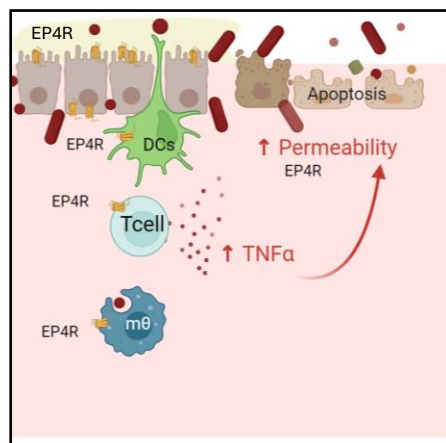
Disease Rationale

- 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.

Progress

- **FTIH SAD/MAD studies have completed**
 - No concerning adverse events noted to date
 - UC patient cohort is underway and indomethacin challenge model is due to start in Sep25
 - Biomarker data analysis from Ph1 studies is ongoing to inform project strategy
 - Input sought from Clinical Advisory Board on emerging clinical and target engagement data

Improved barrier repair & homeostasis
↓ permeability



Created with BioRender.com

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)



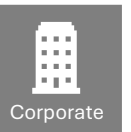
03

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



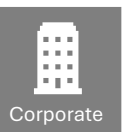
04

Investment in systems and applications for efficiency and scalability
















05

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





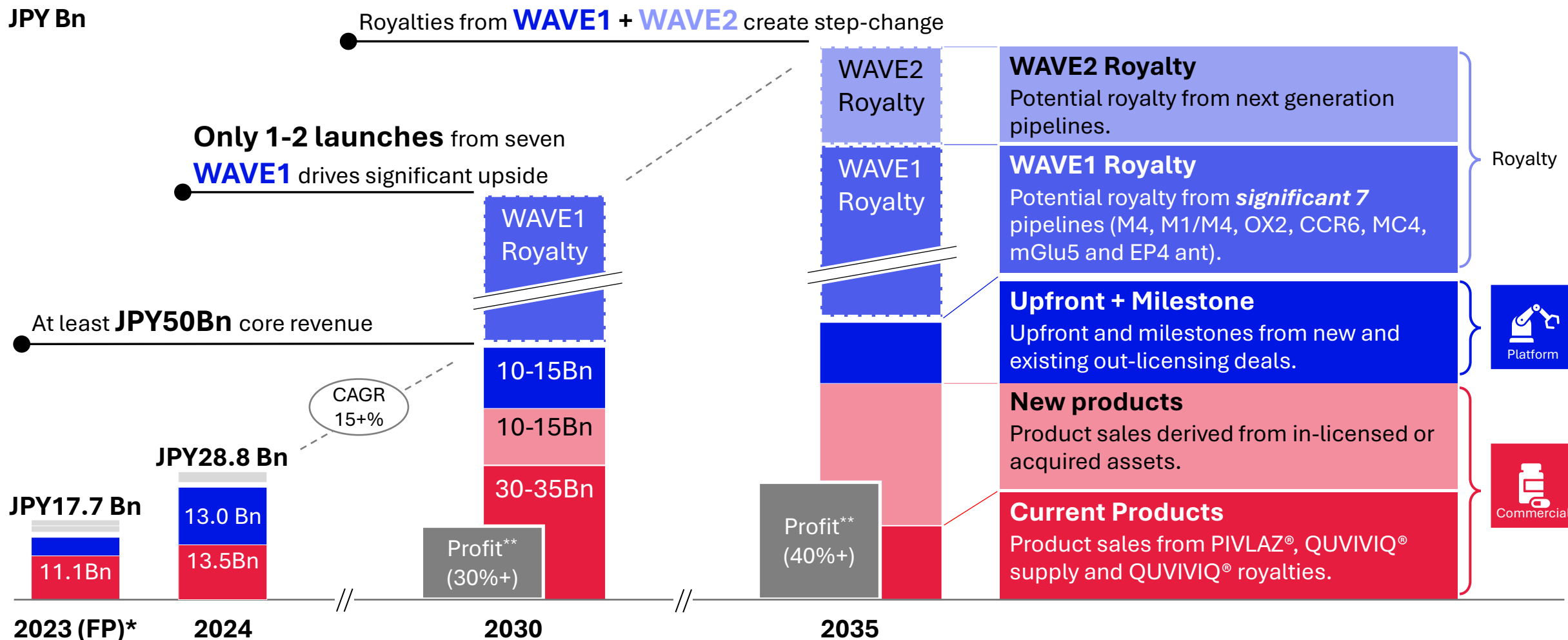
Partner's Wave 1 and Wave 2 programs are positioned across fast growing disease areas of healthcare

	MARKET SIZE (2030)	WAVE1 (Potential Launch by 2030)	WAVE2 (Potential Launch by 2035)
Neurology	\$120bn+	 TEMPERO BIO™ P2 mGlu5 NAM Substance Use Disorders  CENTESSA P2 Ox2 agonist Narcolepsy  NEUROCRINE™ P3 M4 agonist Schizophrenia P2 M4 agonist Bipolar Mania P1 M1/M4 agonist Schizophrenia	 CENTESSA PreC Ox2 agonists Neuropsych-related sleep disorders  NEUROCRINE™ P1 M4 pref. agonist P1 M1 pref. agonist Cognitive & psychosis-related disorders  NXER P1 GPR52 agonist Schizophrenia  abbvie Disc Multiple targets Neurology
Metabolic	\$150bn+	 P1 MC4 antagonist Malnutrition	 Disc Multiple targets T2D/Obesity and Others
Immunology / GI	\$300bn+	 Pfizer P1 CCR6 antagonist IBD  NXER P1 EP4 antagonist + PD-L1 Immune-oncology for Advanced Solid Tumors  CANCER RESEARCH UK	 NXER P1 EP4 agonist IBD
		JPY170bn (max total royalty potential at peak)	Multi billion USD milestones and royalties



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

JPY Bn



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*

✓ : Progress in 2025

PROGRAM	PARTNER	TIMING	EVENT
✓ Cenerimod		Feb. 2025	Assignment of JAPAC rights (excl. China)
✓ TMP-301 (mGlu5 NAM)		Mar. 2025	Phase 2 study start in alcohol use disorder
✓ NBI'568 (M4 agonist)		Apr. 2025	Phase 3 study start in Schizophrenia
NXE'732 (EP4 antagonist)		<u>H2 2025</u>	Phase 2a study start in Advancing Solid Tumours
NBI'568 (M4 agonist)		H2 2025	Phase 2 study start in Bipolar Mania
NBI'570 (M1/M4 agonist)		H2 2025	Phase 2 study start in Schizophrenia
NXE'744 (EP4 agonist)		H2 2025	Phase 2 study start in IBD
NXE'149 (GPR52 agonist)		H2 2025	Phase 1b completion
NXE'732 (EP4 antagonist)		H2 2025	Phase 1b topline data
ORX750 (OX2 agonist)		H2 2025	Phase 2 data readout (NT1/NT2/IH)
Lucerastat		<u>H2 2025</u>	Exclusive opt-in decision
TMP-301 (mGlu5 NAM)		End 2025	Phase 2 result in alcohol use disorder
✓ Multiple discovery collaboration progress		Jun. 2025 (Lilly)	Progression through discovery stage
NBI'567 (M1 ago) / NBI'569 (M4 ago) / NBI'570 (M1/M4 ago)		2025	Phase 1 data readout
✓ QUVIVIQ®		Feb. 2025	Out licensing in Taiwan
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

Underlined text indicates changes from the financial results briefing materials for the fiscal year ended 24/12.

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



Questions?



















Appendix

06














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							
Energair® Breezhaler®	LAMA+LABA+ICS	SME	Asthma	 NOVARTIS							
ORAVI®	Antifungal agent miconazole	SME	Oropharyngeal candidiasis	 HISAMITSU							
Cenerimod	S1P ₁ receptor modulator	SME	SLE	 VIATRIS™							
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							
(Not disclosed)	CGRP antagonist	SME	Neurology diseases	 Pfizer							
(Not disclosed)	Multi target	SME/LME	Multiple indications	 Genentech <small>A Member of the Roche Group</small>							
(Not disclosed)	Multi target	SME	Neurology	 abbvie							
(Not disclosed)	Multi target	SME	Diabetes/Metabolic	 Lilly							

Note: SME = small molecule. LME = large molecule. Seebri®, Ultibro®, Energair® 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	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
(Not disclosed)	AI-Augmented Drug Discovery	SME	Neurology diseases	 PHARMENABLE	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
(Not disclosed)	Multi target	SME/LME	Immune / Neurology diseases	 precisionLife <small>improving health - for everyone</small>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
Co-owned companies											
TMP-301	mGlu5 NAM	SME	Alcohol use disorder	 TEMPERO BIO™	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
TMP-301	mGlu5 NAM	SME	Cocaine use disorder	 TEMPERO BIO™	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
ORX750	OX2 agonist (Oral)	SME	Narcolepsy Type 1/2, IH	 CENTESSA <small>PHARMACEUTICALS</small>  Orexia <small>Therapeutics</small>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
ORX142	OX2 agonist (Oral)	SME	EDS in neurology	 CENTESSA <small>PHARMACEUTICALS</small>  Orexia <small>Therapeutics</small>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
ORX489	OX2 agonist (Oral)	SME	Neurology	 CENTESSA <small>PHARMACEUTICALS</small>  Orexia <small>Therapeutics</small>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>

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								
QUVIVIQ®	Dual Orexin antagonist	SME	Insomnia								
NXE0048149 ¹	GPR52 agonist	SME	Neurology diseases								
NXE0039732 ²	EP4 antagonist	SME	Immuno-oncology								
NXE0033744	EP4 agonist	SME	Inflammatory bowel disease								
NXE0027477	GPR35 agonist	SME	Inflammatory bowel disease								
(Not disclosed)	Muscarinic M1 agonist (JP)	SME	Neurology diseases								
(Not disclosed)	SARS CoV-2 Mpro	SME	Coronaviruses								
Multiple programs	Not disclosed	SME/LME	Neurology diseases								
Multiple programs	Not disclosed	SME/LME	GI and Inflammatory diseases								
Multiple programs	Not disclosed	SME/LME	Immunology diseases								
In-house Programs (No longer internally funded. Targeting academic / industrial partnership)											
NXE'310	SSTR5 agonist	Peptide	Hypoglycaemic disorders								
NXE'097	GLP-1 antagonist	Peptide	Hypoglycaemic disorders								
NXE'023	Dual GLP-2/GLP-1 agonist	Peptide	Intestinal failure/NASH								
(Not disclosed)	Apelin agonist	Peptide	Pulmonary Arterial Hypertension								
NXE'641	Dual orexin antagonist	SME	Insomnia and sleep disorders								
(Not disclosed)	PAR-2 mAb	mAb	Atopic Dermatitis/Pain								

Note: SME = small molecule, LME = large molecule.

1: Exclusive license-out option

2: NXE0039732 (EP4 antagonist) is categorized as an in-house asset as we have not licensed out. Under the Clinical Trial and Licence Agreement (CTLA) in 2022, Cancer Research UK sponsors, designs and executes a Phase I/IIa clinical trial of NXE0039732, and NXE holds a licence to the results generated under the trial to continue the clinical development and commercialization of NXE0039732.



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-1117568	M4 agonist	Schizophrenia	Ph3	284	Yes	2025-05-08	2027-10	2025-07-30	NCT06963034	-
NBI-1117568	M4 agonist	Schizophrenia	Ph3	284	Yes	2025-08	2027-11	2025-08-05	NCT07105098	-
NBI-1117569	M4 preferring agonist	Neurology diseases	Ph1	-	-	-	-	-	-	-
NBI-1117570	M1/M4 agonist	Neurology diseases	Ph1	-	No	2024-03-11	2025-09-04	2025-03-14	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	2025-07-01	NCT05549323	NCT06327880 NCT04388878 NCT07009353
PF-07258669	MC4 antagonist	Malnutrition	Ph1	26	No	2024-12-11	2025-02-20	2025-03-07	NCT06706869	NCT04628793 NCT05113940 NCT07086664
TMP-301	mGlu5 NAM	Alcohol use disorder	Ph2	100	Yes	2024-11-14	2025-11-15	2025-07-02	NCT06648655	-
TMP-301	mGlu5 NAM	Cocaine use disorder	Ph1	18	Yes	2025-01-04	2025-05-05	2025-05-18	NCT06648668	-
ORX750	OX2 agonist	Narcolepsy Type 1/2, IH	Ph2	78	Yes	2024-12-23	2025-12	2025-06-04	NCT06752668	NCT07096674
ORX142	OX2 agonist	Neurological & Neurodegenerative Disorders	Ph1	208	No	2025-6-30	2025-12-31	2025-12-31	NCT07082829	-
Generimod	SIP1 modulator	Lupus Erythematosus, Systemic	Ph3	420	Yes	2022-12-13	2026-10-31	2025-06-19	NCT05648500	NCT06475742
			Ph3	420	Yes	2023-06-26	2026-10-31	2025-06-19	NCT05672576	
NXE0048149	GPR52 agonist	Neurology diseases	Ph1	24	No	2024-06-07	2025-11-15	2024-11-05	ISRCTN44913564	ISRCTN17231793
NXE0039732	EP4 antagonist	Immuno-oncology	Ph1/2	150	Yes	2023-07-13	2027-06	2025-06-08	NCT05944237	-
NXE0033744	EP4 agonist	Inflammatory bowel diseases	Ph1	Up to 220	-	2023-11-24	2026-06-30	2024-05-02	ISRCTN70080074	-

*Primary Completion (Estimated)



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 from 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



Exclusive Opt-in Rights And ROFN/ROFR¹

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

	Program	Mechanism of Action	Indication	Stage	Region
Exclusive Opt-in Right	Lucerastat	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3	APAC (ex-China) ²
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.)

	Cash	Non-cash (Material)
Recurring	Costs under “Core”	
Non-recurring (Material)		Costs under “IFRS”

Operating Profit “IFRS”

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



Exchange Rate, Intangible Assets and Non-core Costs

Average exchange rate during period

		FY2025	FY2024	FY2023	FY2022
USD:JPY	Actual	-	151.43	140.53	131.30
	Estimate	152	140	143	
GRP:JPY	Actual	-	193.49	174.81	161.76
	Estimate	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

Shareholdings

(%)

	FY 2024
TemperoBio, Inc	8.863
Centessa	0.70
Biohaven	0.03



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.



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Thank you

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