EXTERNAL
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Corporate Presentation

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

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Agenda

01 Business Overview

02 Strategic Roadmap

03 Our Pipeline

04 Japan/APAC Business

05 Our NxWave™ Platform

06 Financial Results

07 Appendix

Business Overview

01

We are Nxera Pharma

A technology-powered biopharma in pursuit of new specialty medicines to improve the lives of patients

OVERVIEW

$200m	Annual Revenues
$240m	Cash on Hand to Invest
400+	Employees in 5 locations
4565 (Ticker)	Tokyo Stock Exchange PRIME listed
6%+	Japan Govt. top long-term holder

PRODUCTS AND PROGRAMS

Sales

3	In Japan
1	In Global **(with Partner)**

Clinical (Global)

13	**With Partners**
3	In-House

Discovery

20+	In House and **With Partners**

PRODUCT FOCUS & SCIENCE

Market Size Of Product Focus

$120bn+	Neurology
$150bn+	Metabolic
$300bn+	Immunology/ GI

100+	GPCR Structures Solved with NxWave™ Platform
1,500	Patents Granted

Not a traditional Japanese pharma. We think and innovate globally, and specialize locally

Global Drug Discovery Center

CEO | Research | Finance | Chief of Staff

Research & Early Clinical

- Cryo-EM Nobel Prize winning founder
- Proprietary StaR™ and NxWave™
- Structure-based drug design platform

Technical Operations

- Global CMC Operations
- Supply Chain
- Quality Management

Japan Operations Team

Finance | Development / Medical | Operation

Compliance | Commercial

Development & Commercial

- Bilingual management with global experience
- Agile, technology-enabled teams
- Novel go-to-market approaches

Our team is committed to addressing some of the biggest healthcare challenges globally

Strategic Roadmap

02

Our History

Strategic steps taken to build Nxera over the last two decades

2000s

Launched a public company dedicated to **bringing innovation to Japan**

- ✓ IPO on TSE (MOTHERS) in 2004

Made strategic acquisitions to bring **steady revenue** through groundbreaking medicines

- ✓ $186m acquisition of Arakis Limited in 2005
- ✓ Royalty revenues from Breezhaler® medicines from 2012 to present

ARAKIS

2015

Out-licensed several programs to global pharma to **generate profit, a cash reserve and a larger market valuation**

- ✓ 15+ partnered programs that generate upfront and milestone revenue (plus future royalties)

Invested in research-focused companies that could **generate a continuous pipeline of new medicines**

- ✓ $400m acquisition of Heptares Therapeutics Limited in 2015

HEPTARES therapeutics

2023

Elevated our status in the **Tokyo Stock Exchange**, improving access to institutional investors

- ✓ Promotion to TSE (PRIME) segment in 2023
- ✓ First public healthcare investment by the Japan Investment Corporation in 2023

Acquired a commercial-stage pharmaceutical company which provided an **integrated platform** for even greater sustainable revenue growth

- ✓ $466m acquisition of Idorsia Pharmaceuticals Japan and Korea
- ✓ Rapidly growing revenues from sales of PIVLAZ®

idorsia JAPAN KOREA

2024

Nxera

Launched new corporate branding:

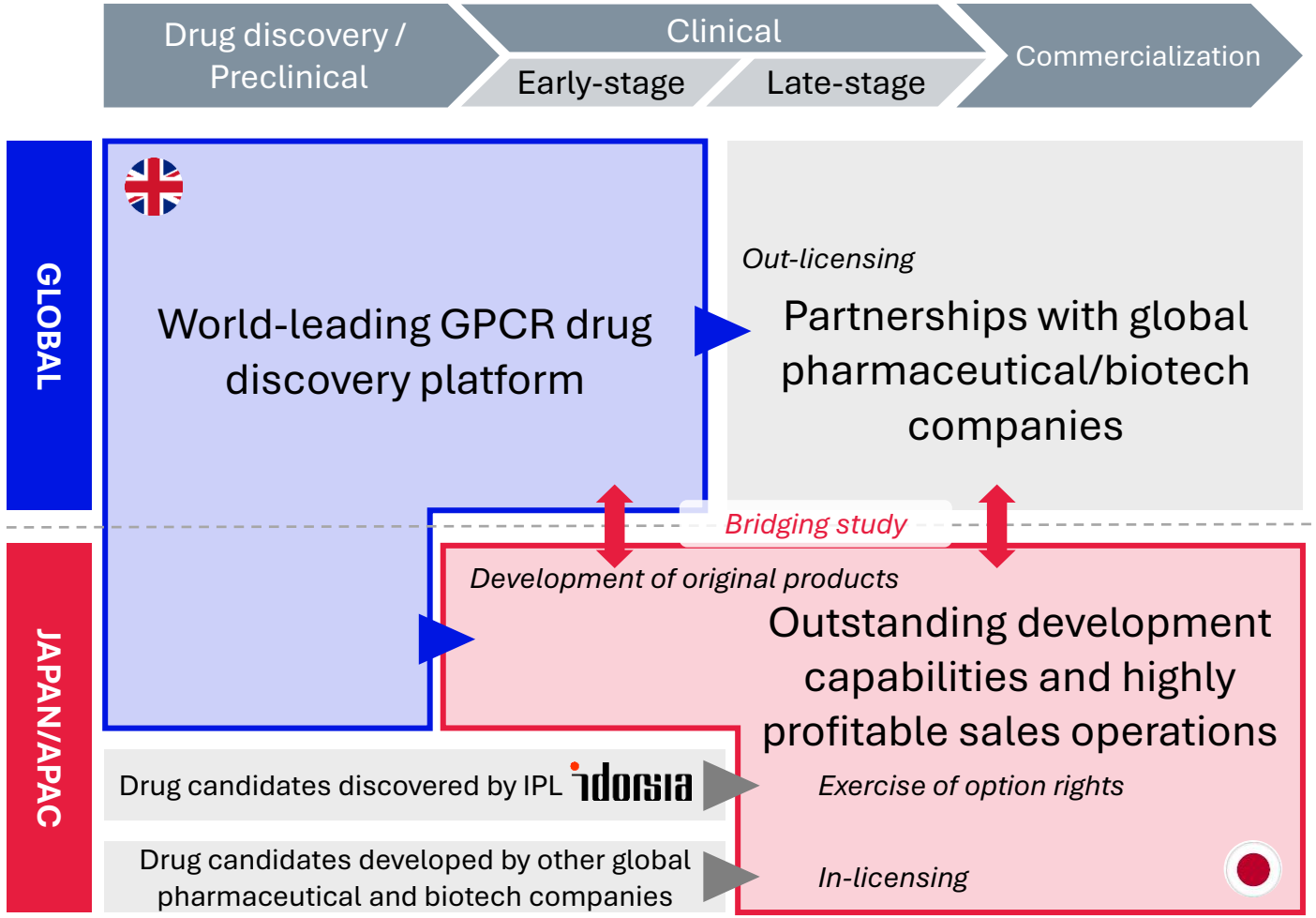
Nxera Pharma Co

With a vision to lead the next era of medicine.

From Japan, for Japan, and the world.

Building a fully integrated biopharma from Japan

Accelerating growth to achieve our mission by leveraging business platform in Japan and UK



Our source of revenue

1. **Upfront payment**
   Received upon a license agreement
2. **Milestone payment**
   Received as R&D/Sales progresses
3. **Royalty**
   Received based on product sales
4. **Product sales**

Business model

Platform

Platform

Commercial

Commercial

Priority objectives for FY2025

01 <u>JPY 17 billion+</u> Net product sales (PIVLAZ® plus QUVIVIQ®) — Commercial

02 Acquire/in-license <u>at least one</u> late-stage medicine for Japan/APAC (ex-China) — Commercial

03 Execute <u>at least one</u> new major partnership, and initiate <u>at least one</u> new in-house Ph.2 study — Platform

04 Investment in systems and applications for efficiency and scalability — Corporate

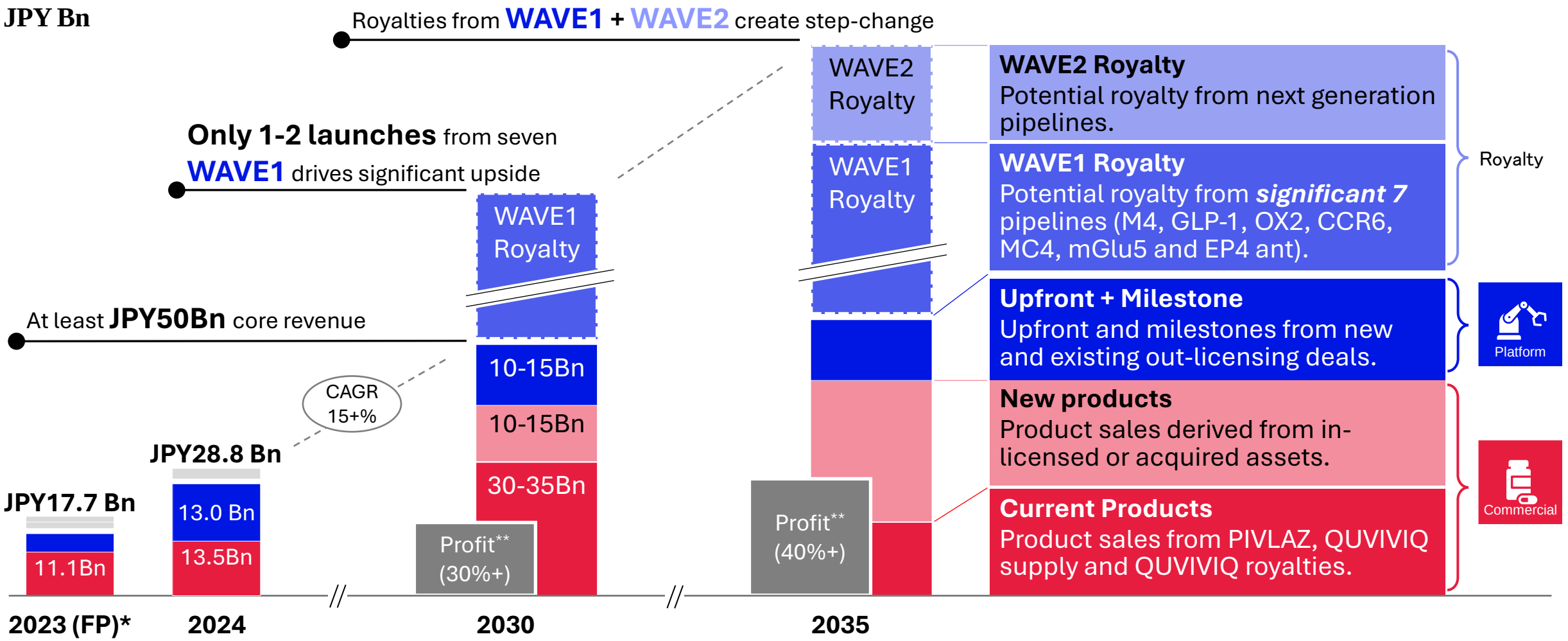
05 <u>Positive operating profit under IFRS (if GPR52 option is exercised)</u> — Corporate

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 PHARMACEUTICALS: P2 Ox2 agonist *Narcolepsy* NEUROCRINE BIOSCIENCES: P3 M4 agonist *Schizophrenia*; P2 M4 agonist *Bipolar Mania*; P1 M1/M4 agonist *Schizophrenia*	CENTESSA PHARMACEUTICALS: PreC Ox2 agonists *Neuropsych-related sleep disorders* NEUROCRINE BIOSCIENCES: P1 M4 pref. agonist; P1 M1 pref. agonist *Cognitive & psychosis -related disorders* Nxera: P1 GPR52 agonist *Schizophrenia* abbvie: Disc Multiple targets *Neurology*
Metabolic	$150bn+	Pfizer: P1 GLP-1 agonist *T2D / Obesity*; P1 MC4 antagonist *Malnutrition*	Lilly: Disc Multiple targets *T2D/Obesity and Others*
Immunology / GI	$300bn+	Pfizer: P1 CCR6 antagonist *IBD* 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.

Our Pipeline

Programs by Design

03

Major pipeline Overview (incl. projections)

	Discovery – Preclinical	Phase 1	Phase 2	Phase 3	Filed	Commercial
IN-HOUSE	10+ PROGRAMS • Immunology • Neuroscience • Gastrointestinal • Metabolic	EP4 ant. NXE'732 ★ Advanced solid tumors (Cancer Research UK)	1H 2025	Lucerastat (A) Fabry disease		PIVLAZ® (A) Cerebral vasospasm
		EP4 ag. NXE'744 IBD	2H 2025			QUVIVIQ™ (A) Insomnia (SHIONOGI)
		GPR52 ag. NXE'149 Schizophrenia (Boehringer Ingelheim)	2026 (current trial complete in 2025)			
PARTNERED	15+ PROGRAMS Key discovery collabs. Lilly Diabetes/Metabolic abbvie Neurology	M_4 pref. ag. NBI'569 Neurology (Neurocrine Biosciences)	M_4 ag. NBI'568 Bipolar Mania (Neurocrine Biosciences)	M_4 ag. NBI'568 Schizophrenia (Neurocrine Biosciences)		Respiratory Portfolio COPD / Asthma (Novartis)
		M_1M_4 ag. NBI'570 Schizophrenia (Neurocrine Biosciences)	2H 2025			
		M_1 pref. ag. NBI'567 (J) Neurology (Neurocrine Biosciences)				
		GLP-1 ag. PF'522 ★ Chronic Weight Management (Pfizer)				
		CCR6 ant. PF'894 ★ IBD (Pfizer)				
		MC4 ant. PF'669 Malnutrition (Pfizer)				
	Key technology collabs. Antiverse AI-driven precisionlife Neurology & Autoimmune	$mGlu_5$ NAM TMP-301 ★ Cocaine use disorder (TEMPERO BIO)	$mGlu_5$ NAM TMP-301 ★ Alcohol use disorder (TEMPERO BIO)			
		OX2 ag. ORX142 Neurology (Centessa)	OX2 ag. ORX750 ★ Narcolepsy, IH (Centessa)			
				Cenerimod (A) SLE (Viatris)		

★ : Data readouts anticipated in 2025
: Exclusive license-out option
: Exclusive license-in option
(A) : Nxera has APAC* rights
(J) : Nxera has Japan rights

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.

Major pipeline Overview (incl. key partner highlights)

	Discovery – Preclinical	Phase 1	Phase 2	Phase 3	Filed	Commercial
IN-HOUSE	10+ PROGRAMS • Immunology • Neuroscience • Gastrointestinal • Metabolic	EP4 ant. NXE'732 Advanced solid tumors (Cancer Research UK) EP4 ag. NXE'744 IBD GPR52 ag. NXE'149 Schizophrenia (Boehringer Ingelheim)		Lucerastat (A) Fabry disease		PIVLAZ® (A) Cerebral vasospasm QUVIVIQ™ (A) Insomnia (SHIONOGI)
PARTNERED	15+ PROGRAMS Key discovery collabs. Lilly Diabetes/Metabolic abbvie Neurology Key technology collabs. Antiverse AI-driven precisionlife Neurology & Autoimmune	M_4 pref. ag. NBI'569 Neurology (Neurocrine Biosciences) M_1M_4 ag. NBI'570 Schizophrenia (Neurocrine Biosciences) M_1 pref. ag. NBI'567 (J) Neurology (Neurocrine Biosciences) GLP-1 ag. PF'522 Chronic Weight Management (Pfizer) CCR6 ant. PF'894 IBD (Pfizer) MC4 ant. PF'669 Malnutrition (Pfizer) $mGlu_5$ NAM TMP-301 Cocaine use disorder (Tempero Bio) OX2 ag. ORX142 Neurology (Centessa)	M_4 ag. NBI'568 Bipolar Mania (Neurocrine Biosciences) Neurocrine Biosciences Total Milestones: $2.6bn Royalties: high-single digit to mid-teens Pfizer Total milestones: $570m Royalties: Mid to high single digits $mGlu_5$ NAM TMP-301 Alcohol use disorder (Tempero Bio) Tempero Bio Royalties: Mid to high single digits OX2 ag. ORX750 Narcolepsy, IH (Centessa)	M_4 ag. NBI'568 Schizophrenia (Neurocrine Biosciences) Cenerimod (A) SLE (Viatris)	Respiratory Portfolio COPD / Asthma (Novartis)	

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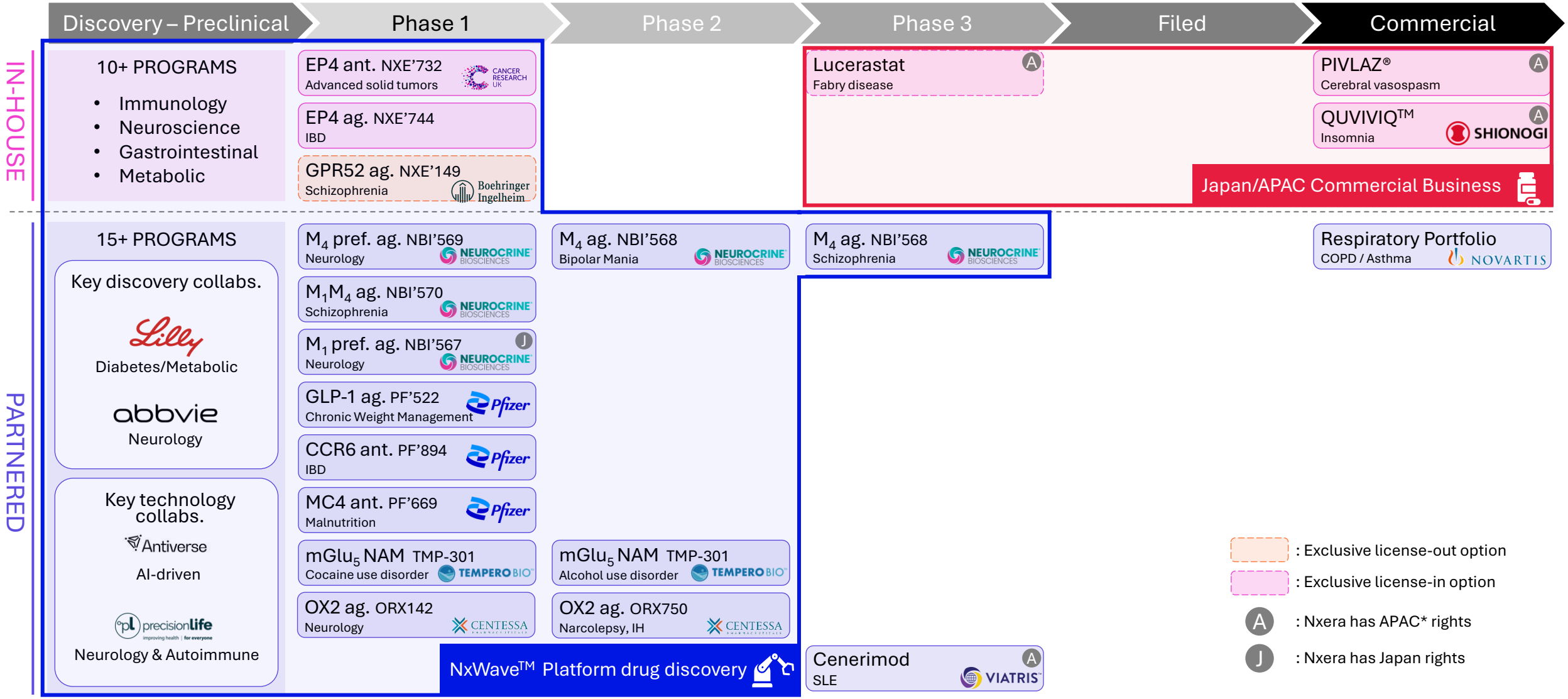
Major pipeline Overview (By business categories)



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Looking ahead to potential catalysts in 2025*

✓ : Progress in 2025

PROGRAM	PARTNER	TIMING	EVENT
✓ Cenerimod	idorsia VIATRIS	Feb. 2025	Assignment of JAPAC rights
✓ TMP-301 (mGlu5 NAM)	TEMPERO BIO	Mar. 2025	Phase 2 study start in alcohol use disorder
✓ NBI'568 (M4 agonist)	NEUROCRINE BIOSCIENCES	Apr. 2025	Phase 3 study start in Schizophrenia
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 Tumours
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 2 data readout (NT1/NT2/IH)
TMP-301 (mGlu5 NAM)	TEMPERO BIO	End 2025	Phase 2 result in alcohol use disorder
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
✓ QUVIVIQ™	Holling Bio-Pharma Corp.	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

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

Nxera

Key strategy for each business category

Maximize the value of each business and demonstrate synergies by conducting integrated development in future

	NxWave™ platform driven	Acquire or in-license for Japan
Organic Growth	■ Collaborate with existing partners to help them to progress pipeline licensed from us ■ Execute at least one new high value collaboration and/or co-investment per year	■ Maximize and optimize sales and profit for two major products (PIVLAZ®/QUVIVIQ™)
Strategic Growth	■ Collaborate/invest in new technologies with synergies	■ In-license late-stage products for clinical development and commercialization in Japan and APAC

Japan/APAC Business

Deliver innovation to patients in Japan/APAC

04

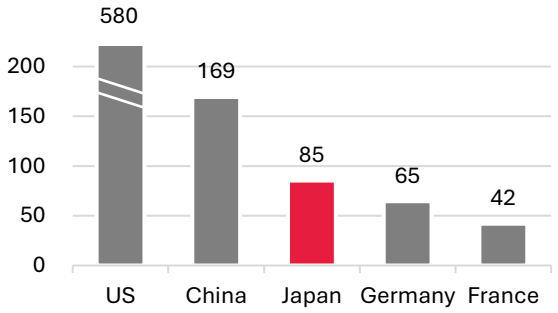
Commercial

Japan will serve as our base to expand across APAC markets

Japan is an attractive, established market with strong volumes

Japan is the second largest pharma market (ex-China)

Market size (USD bn) *(2021)*



Tailwinds from near-term regulatory changes

"Japan Phase 1 Drug Clinical Trials No Longer Needed for Global Clinical Trials"

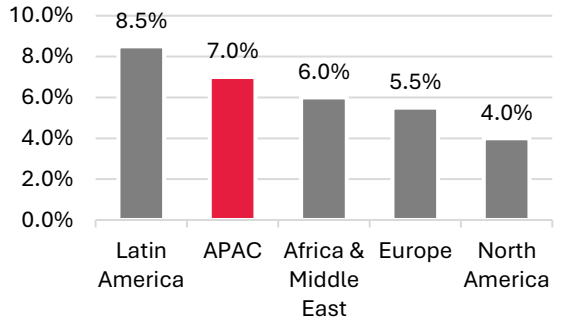
MHLW
Ministry of Health, Labour and Welfare of Japan

High quality clinical and regulatory environment

- ✓ Excellent access to Doctors/HCPs who evaluate novel drugs
- ✓ Typically achieve strong patient uptake
- ✓ Reduces drug loss and drug lag for Japan patients

APAC is the second highest growth pharma market

Market growth (CAGR %) *(2019 - 2027)*



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
APAC (ex-China) territory includes South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

NXera

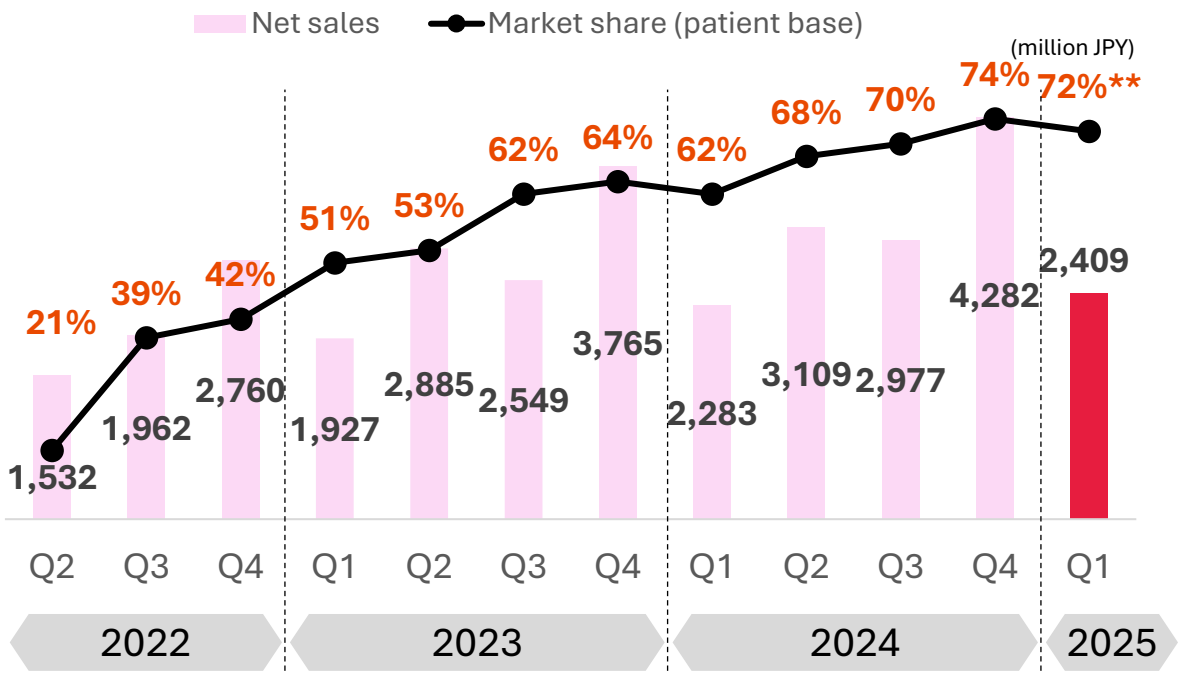
PIVLAZ® (clazosentan, an endothelin A antagonist)

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

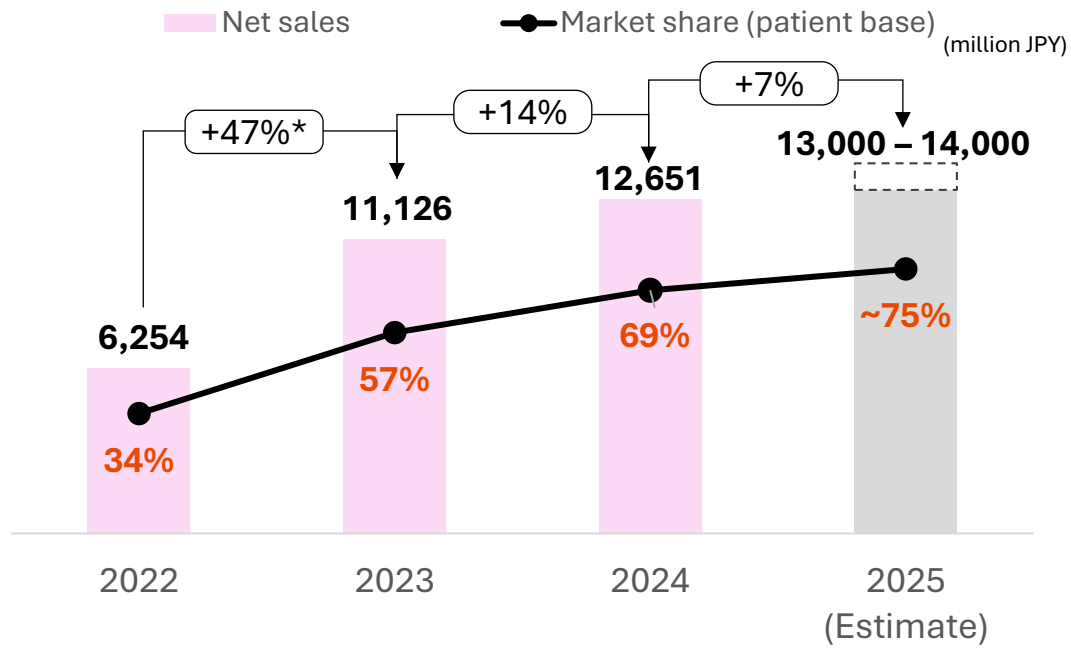
エンドセリン受容体拮抗薬 薬価基準収載
ピヴラッツ® 点滴静注液 150mg

Commercial

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,

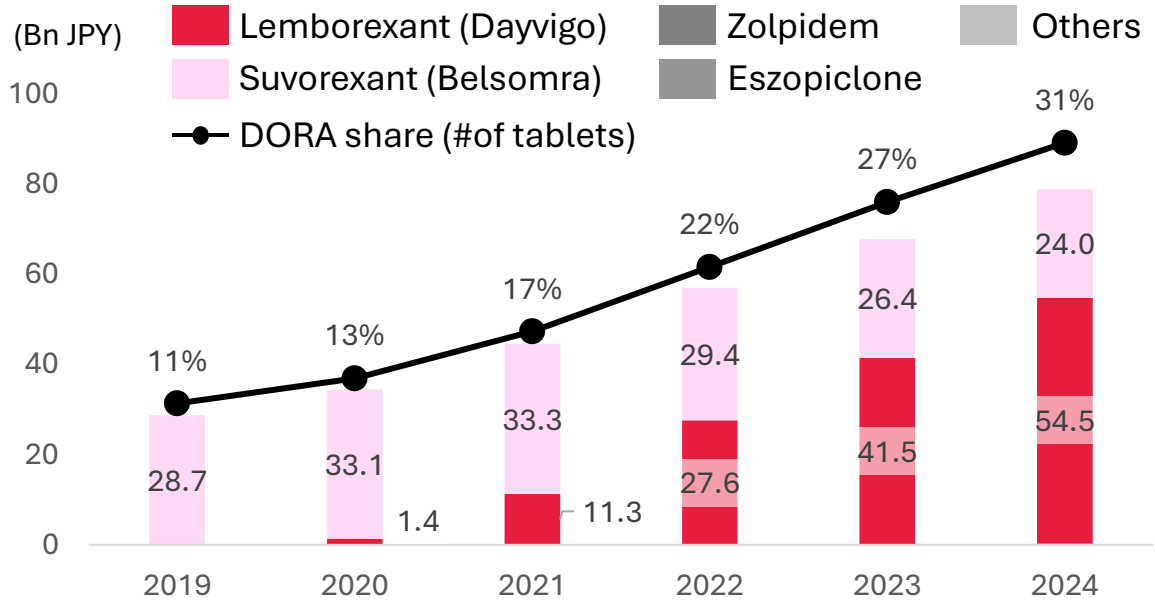
QUVIVIQ™ (daridorexant, dual orexin antagonist "DORA")

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

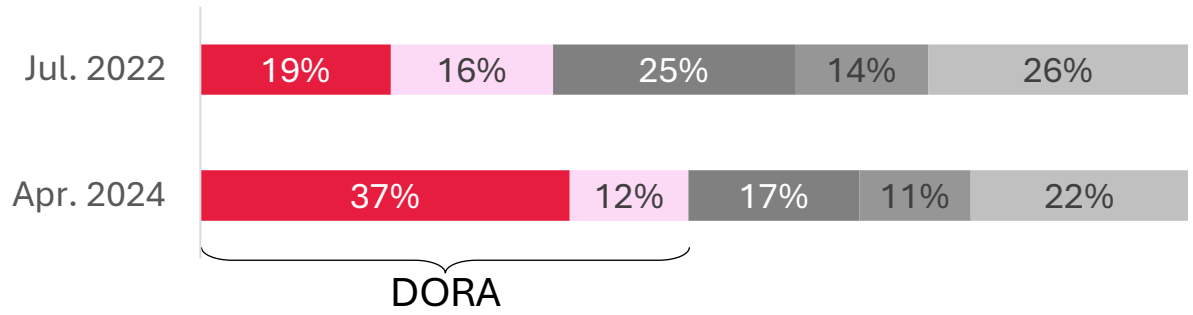
不眠症治療薬 / オレキシン受容体拮抗薬
クービビック®錠 25mg 50mg
薬価基準未収載

Commercial

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

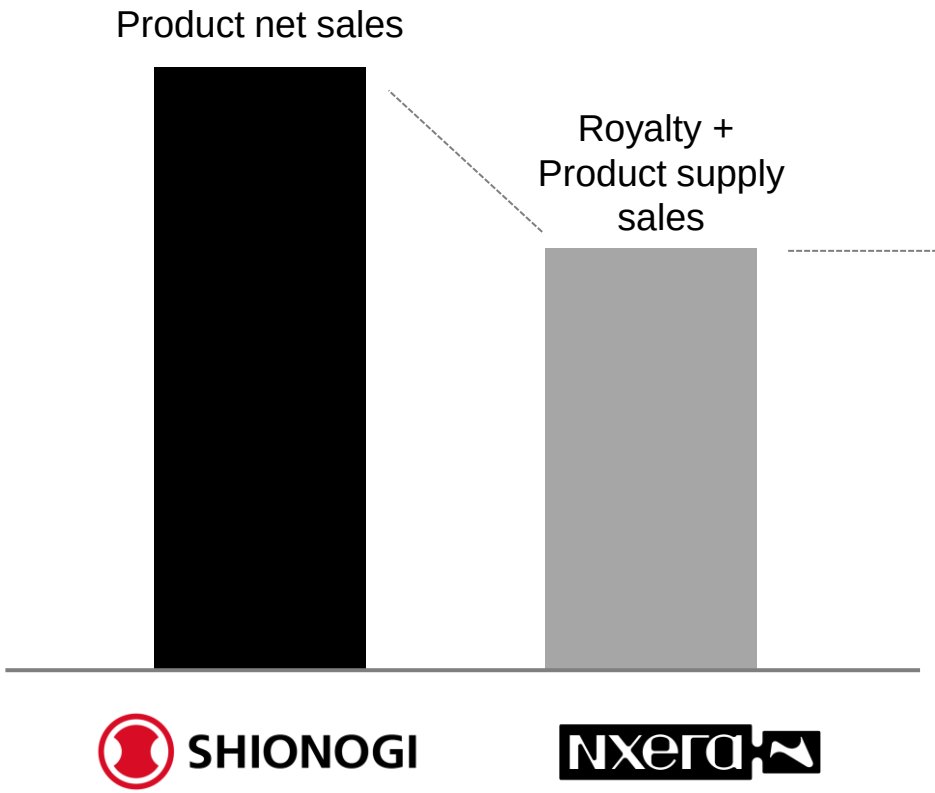
Quviviq Business structure Image for Nxera

Profit starts from royalty and supply margin will be adding on in a few years

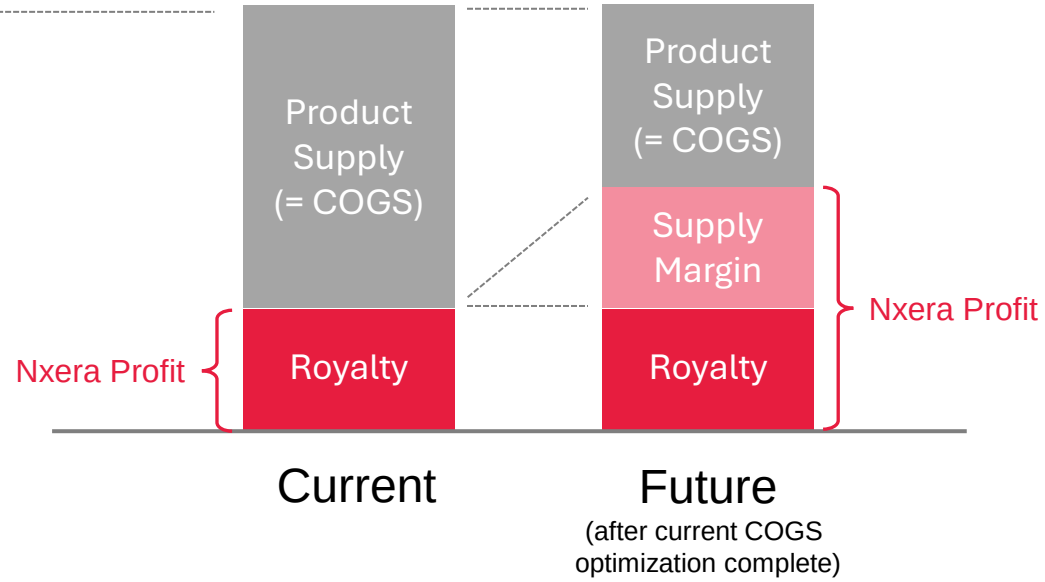
不眠症治療薬 / オレキシン受容体拮抗薬
クービビック®錠 25mg 50mg
薬価基準未収載

Commercial

Sales structure



Profit structure for Nxera



Commercial

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

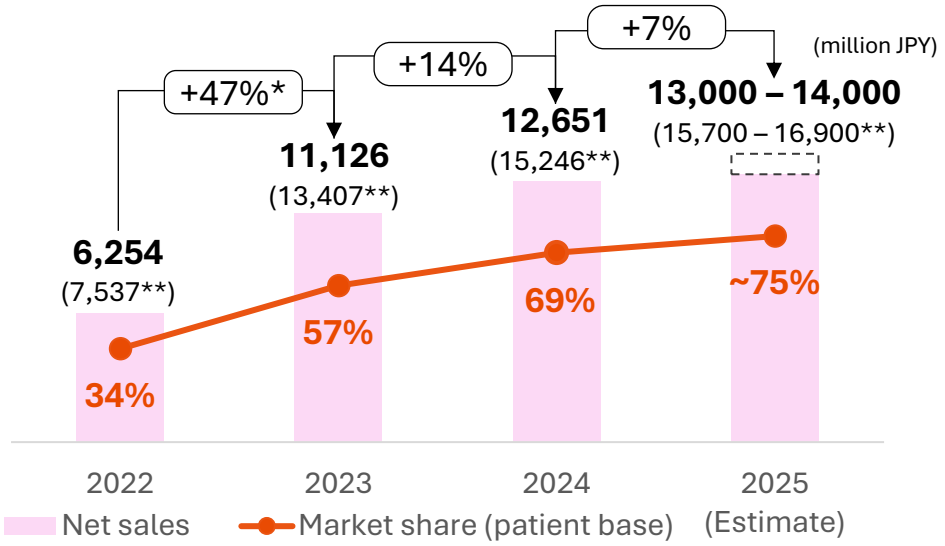
13.0 – 14.0 Bn JPY
(NHI Sales:15.7 – 16.9Bn JPY)

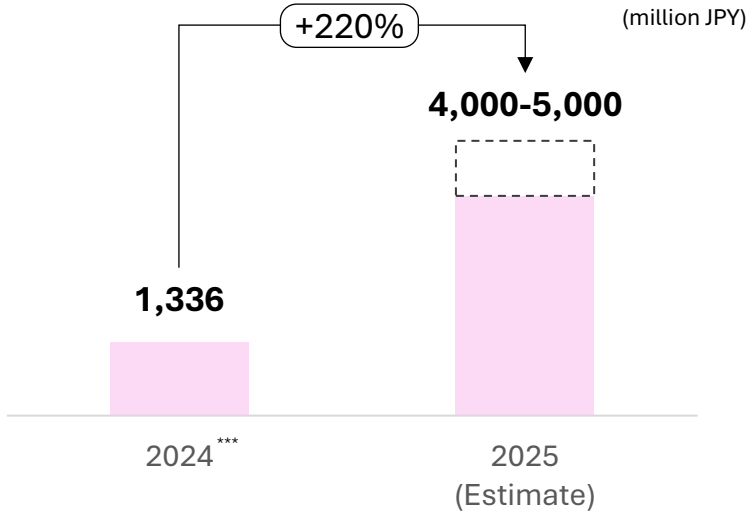
+7%

4.0 – 5.0 Bn JPY
(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

Our NxWave™ Platform

Cutting-edge Science

05

Platform

NxWave™ platform enables faster, cheaper and more precise drug discovery

World-leading science and platform enables efficient drug discovery against difficult targets

	Conventional drug discovery	Our drug discovery
Approach	Empirical design	Rational design (computer-based)
Method	High Throughput Screening (HTS[1])	Proprietary NxWave™ Platform
Period[2]	4.5 years on average	3.0 years on average
Costs[2]	$15 million	$5 million
Features [3]	Difficult to design drugs precisely – high development attrition rate	Execute more precise drug design – lower development attrition rate
Target [3]	Difficult for GPCRs with unstable structures	Best for GPCRs with unstable structures

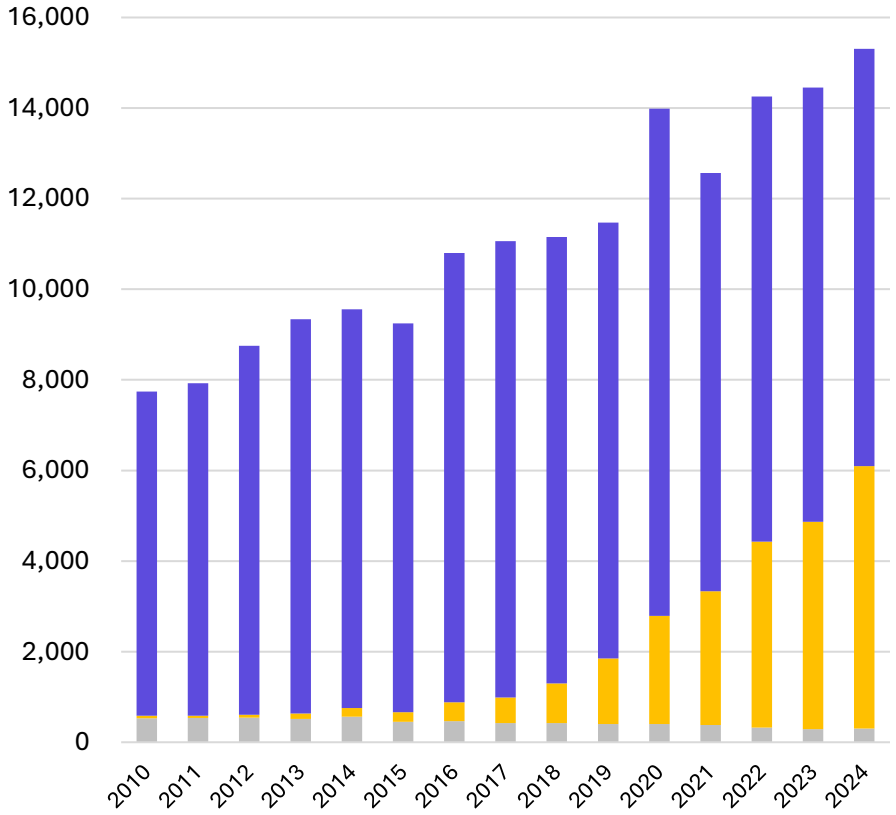
[1] HTS/High Throughput Screening is a method to find drug candidates by reacting tens of thousands to millions of compounds with drug targets using large machines and human hands.
[2] The period from target selection to preclinical testing. For conventional drug discovery, figures are taken from NATURE REVIEWS Drug Discovery (MARCH 2010).
[3] Precise drug design make clear the binding site of target, make easier to improve compound, create backups and redo – potentially increase the success rate. GPCR is most popular drug target which account for 30% of current drug target.

Platform

Number of Structures Solved and Deposited in PDB, Resolution by technology

The number of structures solved using Cryo-EM is increasing, X-ray crystallography has extremely high resolution

Number of stricture solved by technology



X-ray

NXera

Cryo-EM

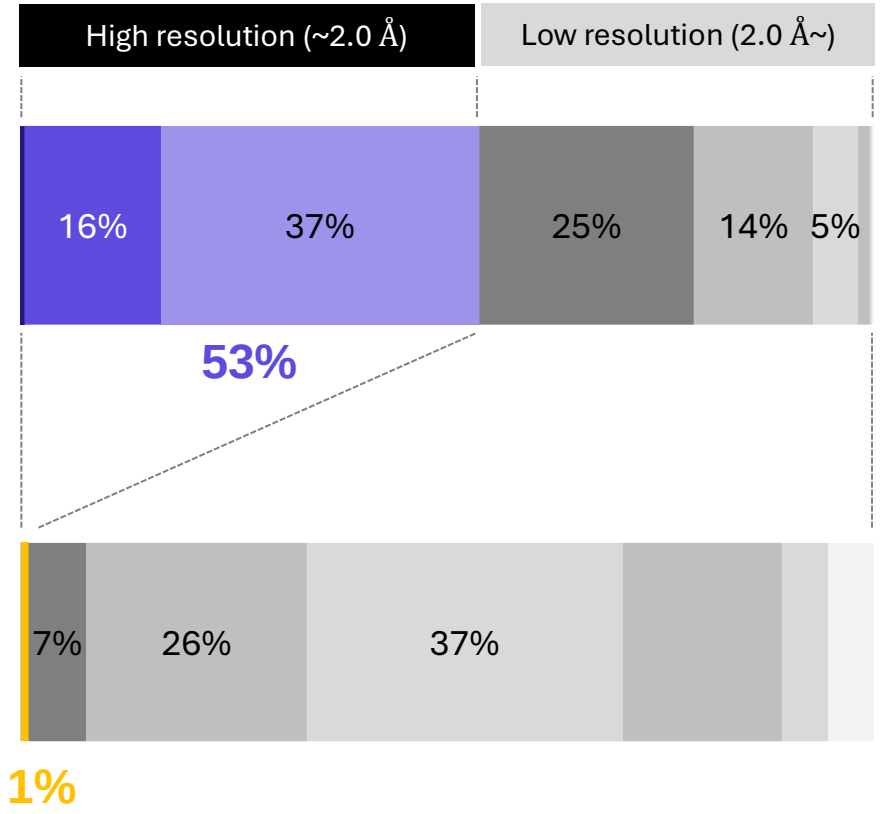
NXera

septerna

TECTONIC Therapeutic

STRUCTURE THERAPEUTICS

Resolution by technology



Source: Protein Databank

NXera

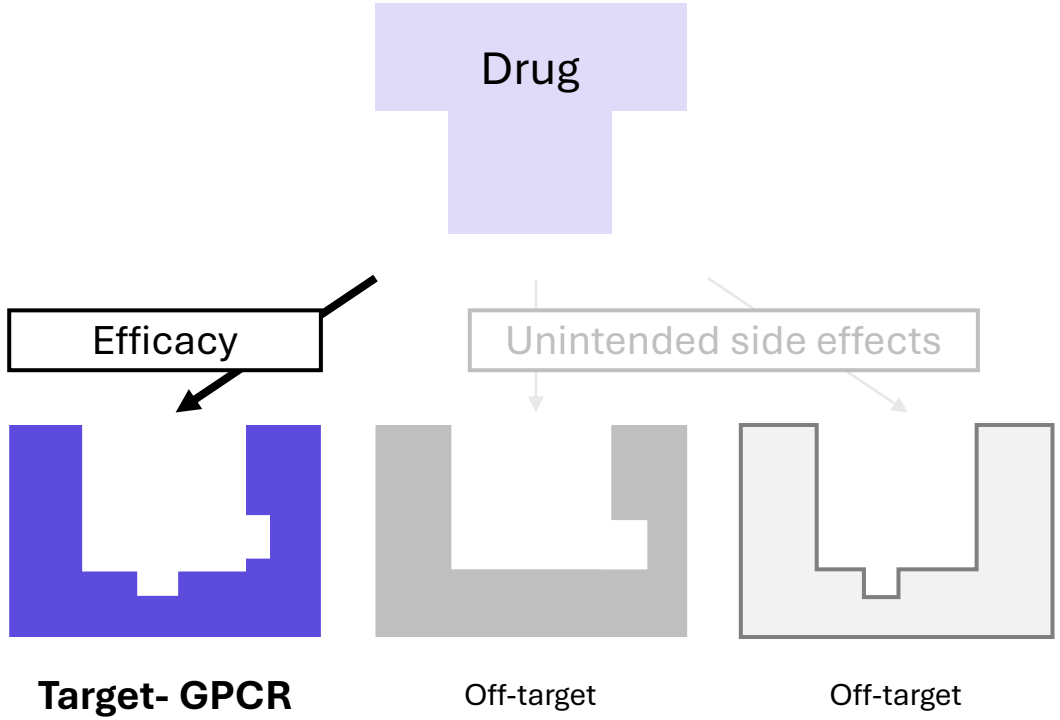
Platform

Our platform enables precise design of GPCR models

Only by performing detailed structural analysis can we design great drugs.

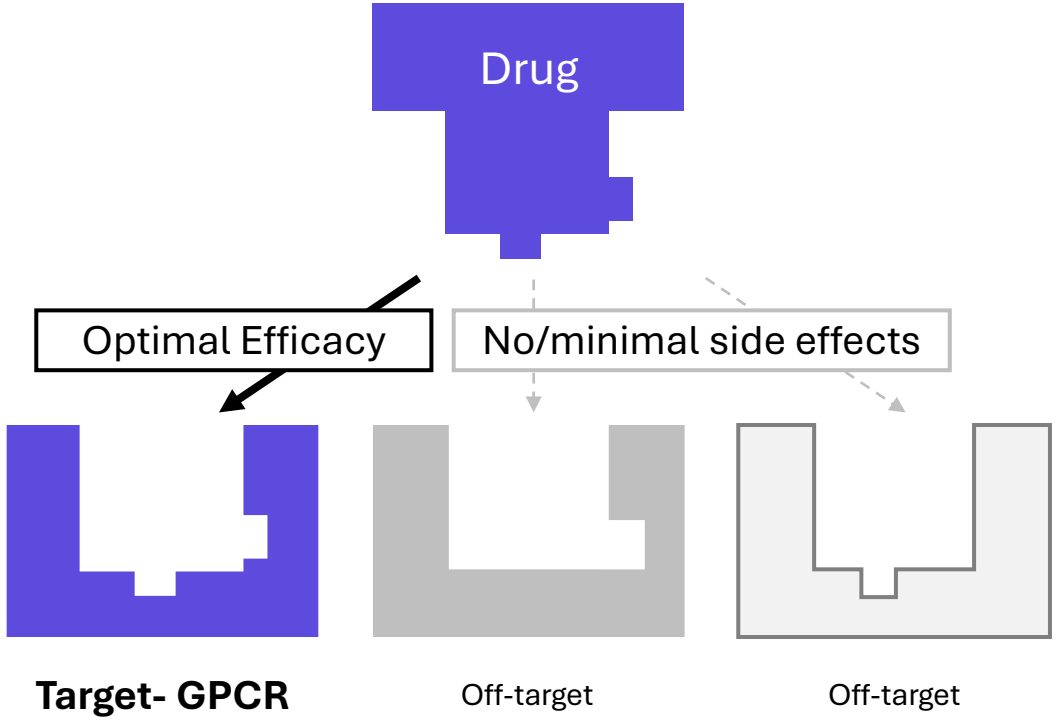
Imprecise GPCR model: **Standard Medicine**

Poorly understood GPCRs (locks) led to suboptimal drugs (keys) being designed



Precise GPCR model: **Optimized Medicine**

High selectivity enables to **optimize efficacy and minimize side effects**

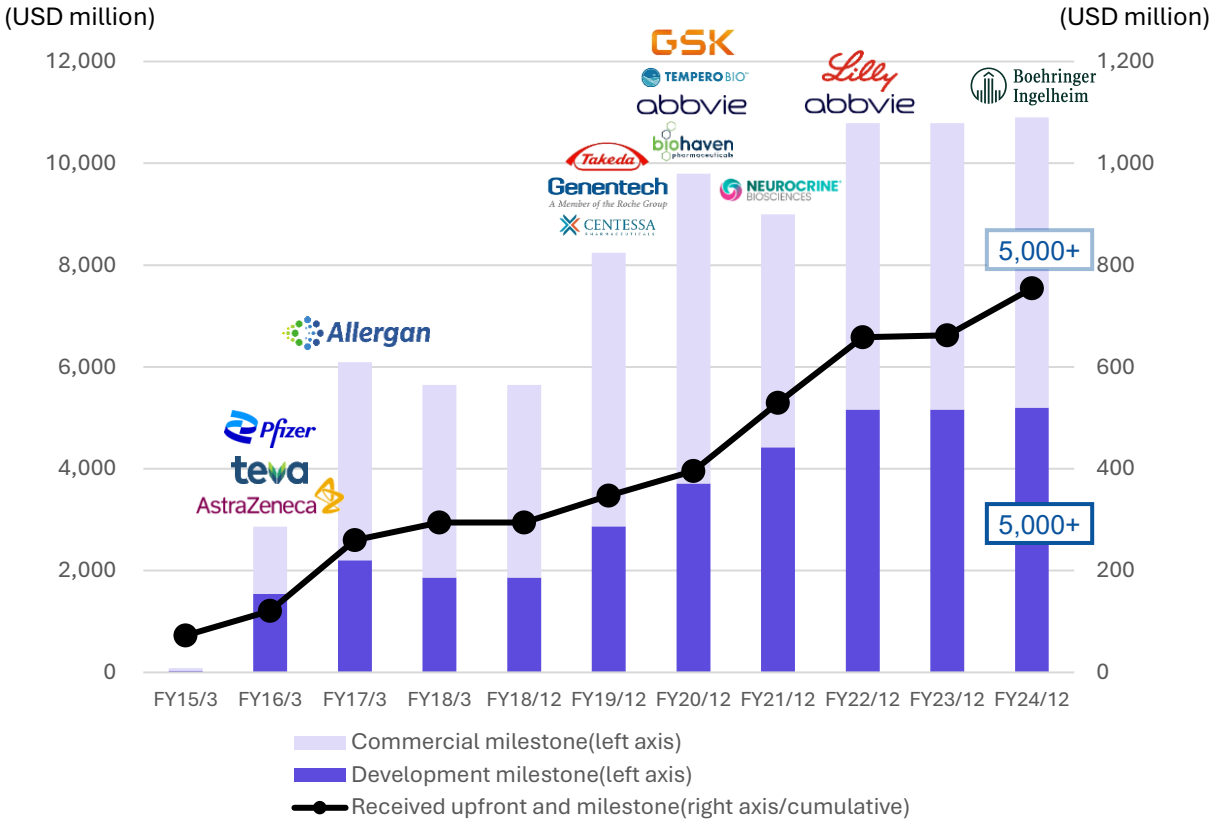


Platform

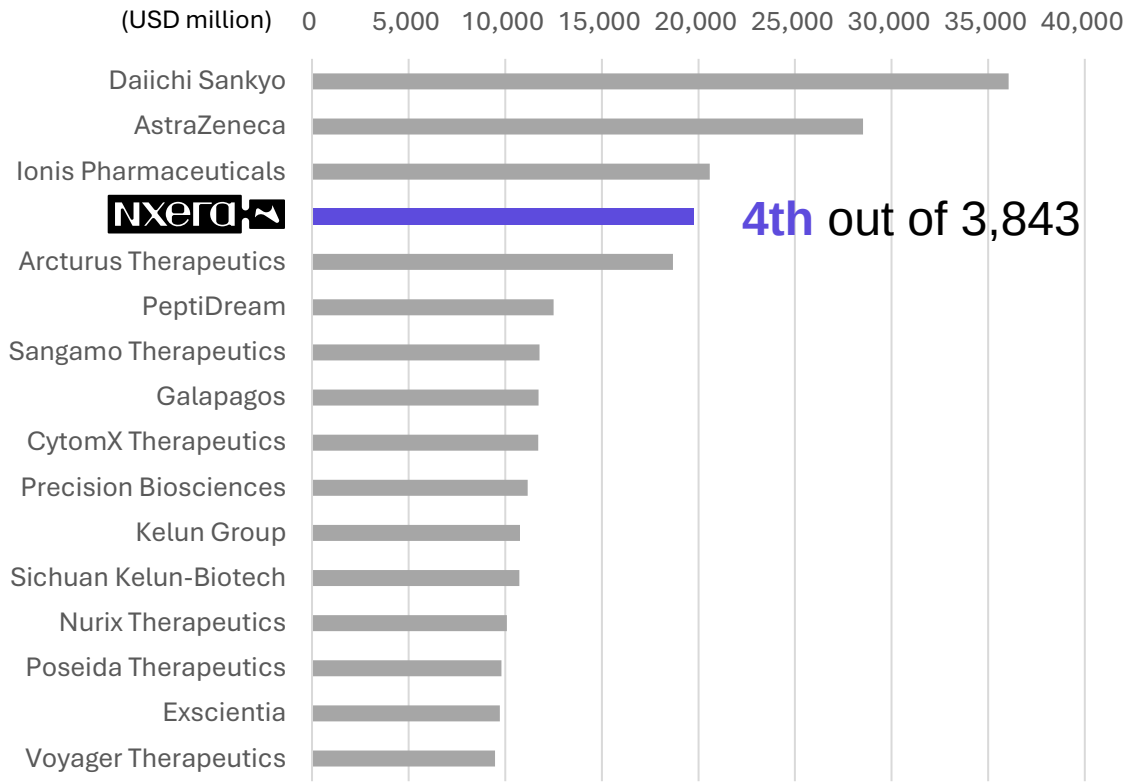
Our track record of major licensing transactions speaks for itself…

Income from licensing provides a great source of non-dilutive financing to support our growth

Balance of potential milestone income from existing license agreements[1]



Top 15 pharmaceutical/biotech companies by license value[2] (cumulative total since 2015)



[1] Balance as of the end of the fiscal year of only those currently under contract. TEVA and AbbVie (formerly Allergan), for which compounds were returned, are excluded from the balances from FY2018 and FY2021, respectively.
[2] The figures are based on 'Licensing' category on third party's (EvaluatePharma's) proprietary database and therefore do not completely match the amounts shown in the LHS chart.
Source: Company's data (LHS) and EvaluatePharma (as of 2024/10/17) (RHS)

Platform

… hundreds of millions of dollars received, billions of dollars in potential to come

New collaboration and exclusive option to license agreement executed with Boehringer Ingelheim

Partner	Execution	Program	Therapeutic Area(s)	Upfront and Initial Milestones	Potential Total Milestone[1]
Boehringer Ingelheim	March 2024	Collaboration and exclusive option-to-license agreement for GPR52 agonist	Schizophrenia	€25m	**€670m**
Lilly	December 2022	Multi-target Collaboration	Diabetes and Metabolic	$37m	**$800m**
abbvie	August 2022	Multi-target Collaboration	Neurological disorders	$80m	**$1.2bn**
NEUROCRINE BIOSCIENCES	December 2021	Collaboration and license agreement for M_4, M_1 and M_1/M_4 dual agonist	Neurological disorders	$100m	**$2.6bn**
GSK	December 2020	Collaboration and license agreement for GPR 35	Gastrointestinal, immunology	$44m	**$480m**
biohaven pharmaceuticals	December 2020	Collaboration and license agreement for CGRP portfolio	Neurology	$10m	**$380m**
abbvie	June 2020	Discovery Collaboration and Option to License[2]	Inflammatory and Autoimmune	$32m	**$400m**
Takeda	August 2019	Multi-target Collaboration	Multiple; Initial focus on Gastrointestinal	$26m	**$1.2bn**
Genentech A Member of the Roche Group	July 2019	Multi-target Collaboration	Multiple	$26m	**$1.0bn**
Pfizer	November 2015	Multi-target Collaboration	Multiple	-	**$1.8bn**

[1]Potential option fees, development, regulatory and commercial milestone payments agreed at the time of transaction. Nxera is also eligible to receive tiered royalties ranging from high single digit to mid-teen percentage on future net sales of any products developed under the partnership. [2] AbbVie has the option to expand the collaboration by an additional three targets

Nxera

Topline Results for Phase 2 Trial of M4 Agonist

20mg dose demonstrated statistically significant efficacy at Week 3, 4, 5 and 6 vs. placebo

Platform

Once-Daily 20mg Dose Met Primary Endpoint

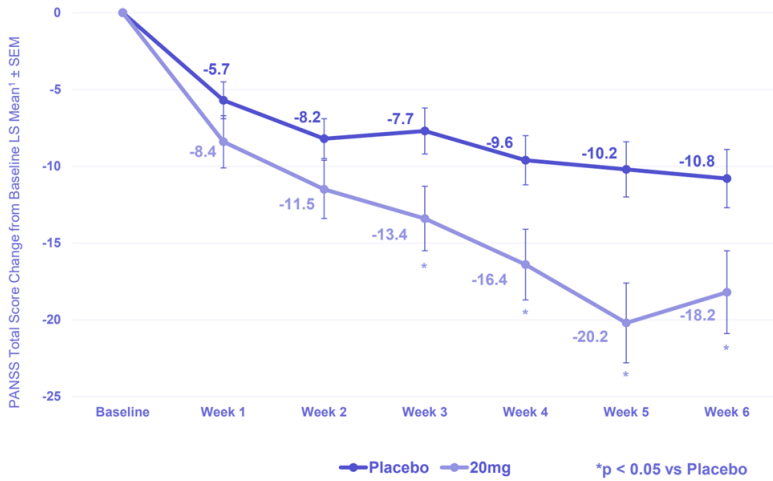
PANSS Total Score vs Placebo

Week 6	Placebo N=68	20mg QD N=35	40mg QD N=38	60mg QD N=34	30mg BID N=26
PANSS Total Score					
LS Mean Change from Baseline*	-10.8	-18.2	-12.6	-13.7	-15.8
LS Mean Difference vs. Placebo, p-value*		-7.5 p = 0.011	-1.9 p = 0.282	-2.9 p = 0.189	-5.0 p = 0.090
Effect Size**		0.61	0.27	0.39	0.23

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

8

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



20mg QD Efficacy Data
Week 4 – Week 6

Week	4	5	6**
PANSS Total Score			
LS Mean¹	-16.4	-20.2	-18.2
LS Mean Difference vs. Placebo¹	-6.8 p = 0.008	-10.0 p < 0.001	-7.5 p = 0.011
Effect Size²	0.53	0.72	0.61

** Primary Endpoint = Week 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

"The effects with the 20-milligram dose, you see statistical significance between Week 3, 4, 5, and six, meaning that you are seeing a reproducible response here."

Source: Neurocrine presentation – Topline Results for Phase 2 Trial of NBI-1117568 (NBI-'568) in Schizophrenia, August 28, 2024

NEUROCRINE BIOSCIENCES

Platform

Comparison of Study Sites and Duration with Known Muscarinic Programs

Mentioned in a presentation Phase 3 of NBI-568 will be one to one randomization and around 20 sites per study

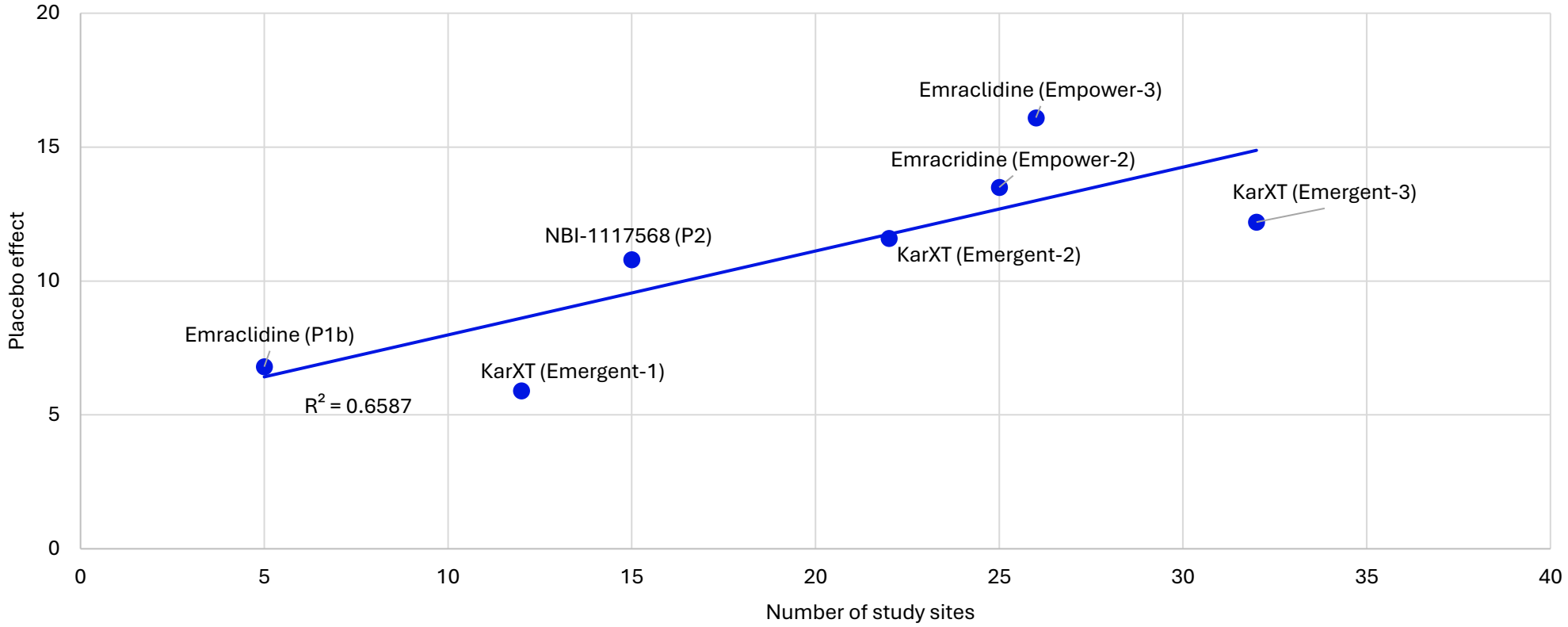
	Neurocrine/Nxera	Neurocrine/Nxera	BMS/Karuna	AbbVie/Cerevel
Compound	NBI-1117568	NBI-1117568	Cobenfy/Kar-XT	CVL-231/Emraclidine
Study name	NCT05545111	NCT06963034	EMERGENT-2/3	EMPOWER-2/3
Route of Administration	oral（once daily）	oral（once daily）	oral（twice daily）	oral（once daily）
Size	213	280+	Total 518	Total 752
Randomization	drug：placebo ＝ 2:1	drug：placebo ＝ 1:1	drug：placebo ＝ 1:1	drug：placebo ＝ 2:1
Number of study sites	15 sites	20 sites (estimate)	22 sites (EMERGENT-2) 32 sites (EMERGENT-3)	26 sites (EMPOWER-2) 25 sites (EMPOWER-3)
Duration	1.8years	2025/5-2027/10(2.2years)	1.6years	2.2years
Phase	Ph2（completed）	Ph3（on trial）	Ph3（completed）	Ph2（unsuccessful）
Primary endpoint	PANSS Total Score Change (Week 6)	PANSS Total Score Change (Week 5)	PANSS Total Score Change (Week 5)	PANSS Total Score Change (Week 5)

NEUROCRINE BIOSCIENCES

Platform

Data comparison of placebo effects (Total PANSS)

Large number of study sites in a clinical trial of muscarinic program may be linked to a higher placebo response.



"Number of facilities is another important factor in managing the placebo effect"

Source: Neurocrine presentation – Topline Results for Phase 2 Trial of NBI-1117568 (NBI-'568) in Schizophrenia, August 28, 2024

NXera

NEUROCRINE BIOSCIENCES

Platform

Safety: Adverse Events Risk

The gastrointestinal and cardiovascular adverse events were higher than placebo in KarXT, but not on 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 trials[20]

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%

	Gastrointestinal (M2)	Cardiovascular (M3)	Others
NBI-568	★ Similar to placebo	Similar to placebo	Somnolence, Dizziness
Cobenfy	★ x3-5 vs. placebo (Four items with 10% or more)	★ x4 vs. placebo (Occurred in 5.9%)	Dry mouth

Source: Neurocrine presentation – Topline Results for Phase 2 Trial of NBI-1117568 (NBI-'568) in Schizophrenia, August 28, 2024, KarXT for Schizophrenia draft evidence report Nov. 28, 2023 (https://icer.org/wp-content/uploads/2023/07/ICER_Schizophrenia_Draft_Report_For-Publication_112823.pdf)

NXera

Financial Results

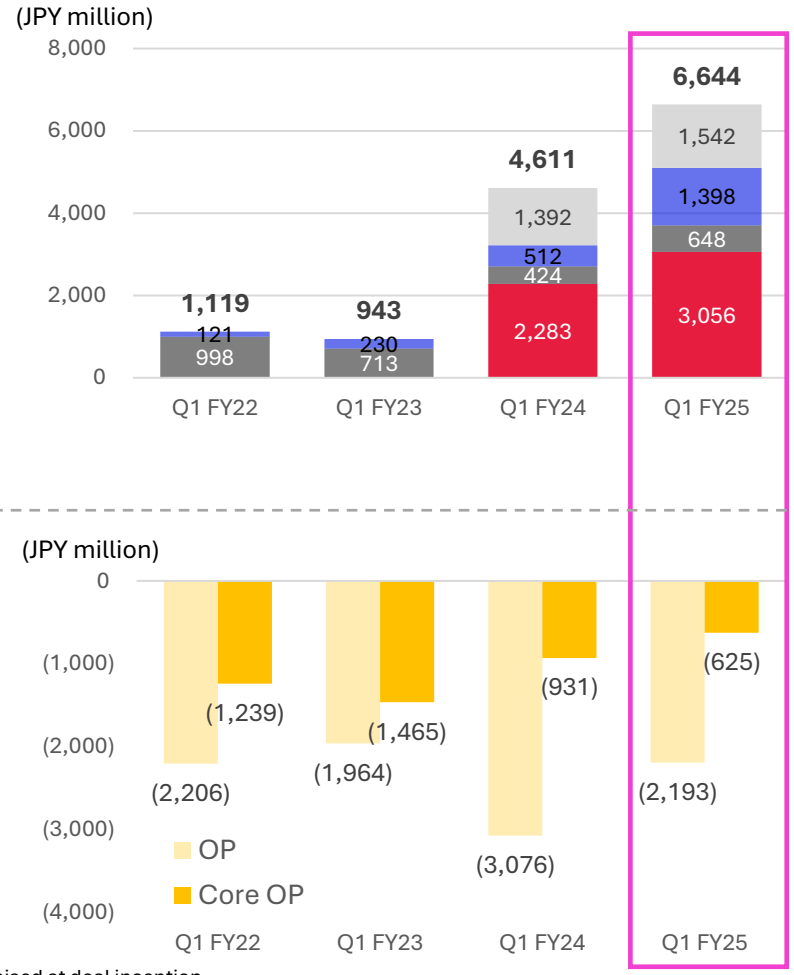
06

Key financial indicators

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

Latest result

Revenue



Operating Profit / Loss

	Major factors
Upfront[1]	USD10m from Viatris for assignment of rights for Cenerimod in Japan and APAC (Feburary).
Milestone[2]	Amount of deferred revenue recognized from existing partners were increased due to robust progression on discovery.
Royalty / Other	Royalties from Respiratory Portfolio with Novartis was increased due to accounting adjustment.
Product Sales	Increase in PIVLAZ® sales (JPY2,409m). Start to record in QUVIVIQ™ product supply and royalty.
R&D	Increased investment in R&D activities for clinical trials.
Cost of Sales	Inclusion of QUVIVIQ™ product supply costs. CoS charge for PIVLAZ® stock not recorded from 1Q 2025.
G&A	Decrease in NPJ/NPK related G&A costs. Amortization of intangible assets (PIVLAZ® and QUVIVIQ™).

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

Breakdown of Q1 results

Business is progressing smoothly. Significant improvement in revenue from commercial

(JPY million)	Platform*1	(YoY)	Commercial*2	(YoY)	Consolidated P&L (Core)	(YoY)	Non-core costs	Consolidated P&L (IFRS)	(YoY)
Revenue	2,046	-12%	4,598	+101%	6,644	+44%	Total : 1,568	6,644	+44%
Cost of Sales	631	+332%	968	+191%	1,599	+234%		1,615	+36%
SG&A	1,189	+17%	1,296	-13%	2,485	-1%	A Amortization (447) B Other (785)	3,701	+1%
R&D	3,178	+27%	294	-21%	3,472	+21%	B Other (336)	3,808	+20%
Other income	293	-24	(6)	-6	287	-30		287	-30
OP/Core OP	**(2,659)**	**-1,637**	**2,034**	**+1,943**	**Core OP (625)**	**+306**		**OP (2,193)**	+883

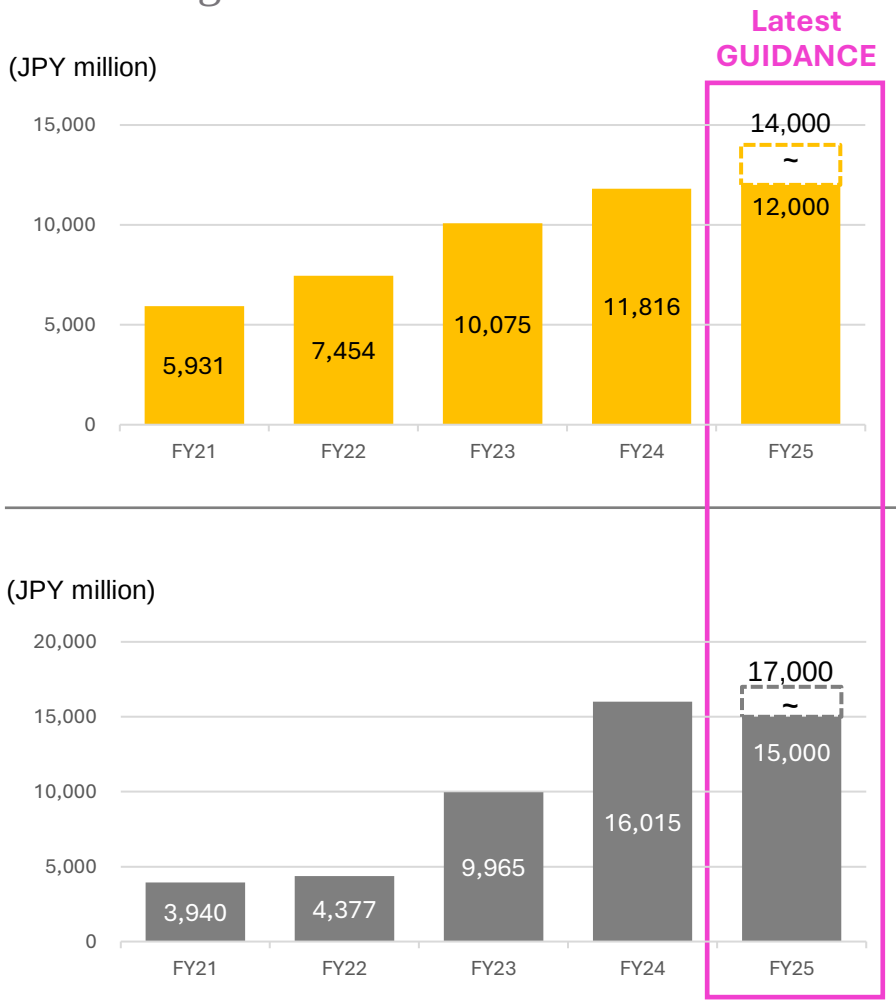
A Amortization of intangible assets (currently relates to PIVLAZ® and QUVIVIQ™).

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

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

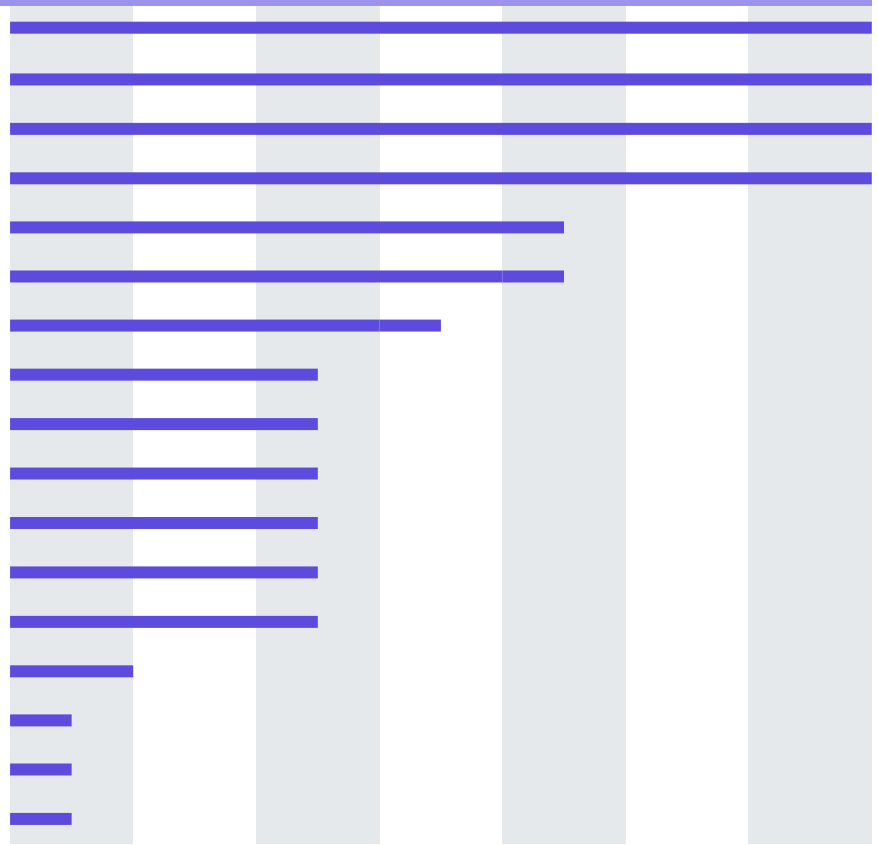
- Investment in technology to increase efficiency and deliver future growth.
- Increase in amortization as QUVIVIQ™ has launched.
- Lower or flat SG&A expenses vs. FY2024 through cost savings.

Appendix

07

Partnered pipeline (1/2)

Compound	Target / Mechanism of Action	Modality	Indication	Partner
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
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
PF-06954522	GLP-1 agonist	SME	Chronic Weight Management	Pfizer
(Not disclosed)	CGRP antagonist	SME	Neurology diseases	Pfizer
(Not disclosed)	Multi target	SME/LME	Multiple indications	Genentech
(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	Alcohol use disorder	TEMPERO BIO							
TMP-301	mGlu5 NAM	SME	Cocaine use disorder	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 [2]	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
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 Nxera 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-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	2025-03-25	NCT05549323	NCT06327880 NCT04388878 NCT07009353
PF-07258669	MC4 antagonist	Malnutrition	Ph1	26	No	2024-12-11	2025-02-20	2025-03-07	NCT06706869	NCT04628793 NCT05113940
PF-06954522	GLP-1 agonist	T2DM/Obesity	Ph1	45	Yes	2024-02-20	2025-04-07	2025-02-13	NCT06279234	NCT06393517 NCT06003777
TMP-301	mGlu5 NAM	Alcohol use disorder	Ph2	100	Yes	2024-11-14	2025-11-15	2025-02-21	NCT06648655	-
TMP-301	mGlu5 NAM	Cocaine use disorder	Ph1	18	Yes	2025-01-04	2025-08-15	2025-03-25	NCT06648668	-
ORX750	OX2 agonist	Narcolepsy Type 1/2, IH	Ph2	78	Yes	2024-12-23	2025-12	2024-04-25	NCT06752668	-
Cenerimod	SIP1 modulator	Lupus Erythematosus,Systemic	Ph3 Ph3	420 420	Yes Yes	2022-12-13 2023-06-26	2026-10-31 2026-10-31	2025-05-25 2025-05-29	NCT05648500 NCT05672576	NCT06475742
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	2026-09	2024-12-02	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 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

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

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"

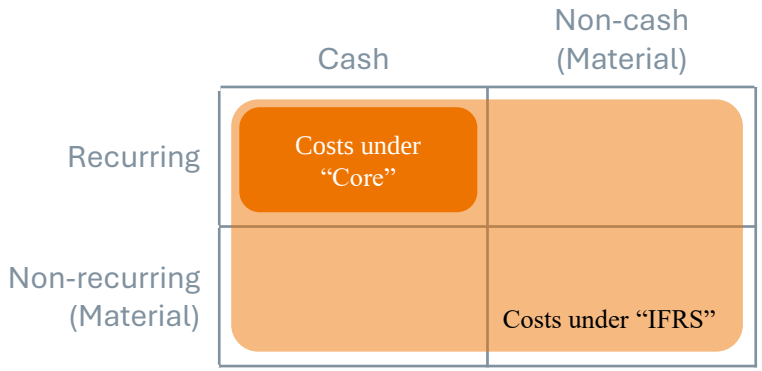
- Core Operating Profit/ Loss is a key financial indicator that highlights the underlying recurring cash generating capability of our business.
- Core Operating Profit/Loss is defined as IFRS Operating Profit + material Non-cash costs + material non-recurring costs
- Material Non-cash Costs include depreciation, 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.)



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.

Locations

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South Korea

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Granta Park,
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United Kingdom

Spaces Grosspeter Tower,
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Switzerland

Thank you