



Building Japan's Next Generation Pharma

42nd Annual J.P. Morgan Healthcare Conference

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References to "FY" in this presentation for periods prior to 1 January 2018 are to the 12-month periods commencing in each case on April 1 of the year indicated and ending on March 31 of the following year, and the 9 month period from April 1 2017 to December 31 2017. From January 1 2018 the Company changed its fiscal year to the 12-month period commencing in each case on January 1. References to "FY" in this presentation should be construed accordingly.

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Building Japan's Next-Generation Pharma Company



 TOKYO STOCK EXCHANGE
 PRIME
 TSE: 4565

 350+ FTE EMPLOYEES

 TOKYO, JAPAN (HQ)
 CAMBRIDGE, UK
 LONDON, UK
 SEOUL, SOUTH KOREA
 BASEL, SWITZERLAND

 REVENUE-GENERATING
 \$350M+ CASH IN HAND
 (DEC-2023)

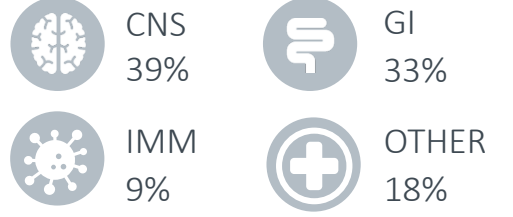
CUTTING-EDGE SCIENCE

**WORLD-LEADERS IN GPCR
STRUCTURE-BASED
DRUG DESIGN**

- STRONG FOCUS ON GPCR TARGETS – SOLVED **375+** MOLECULAR STRUCTURES

PROGRAMS BY DESIGN

30+ ACTIVE PROGRAMS



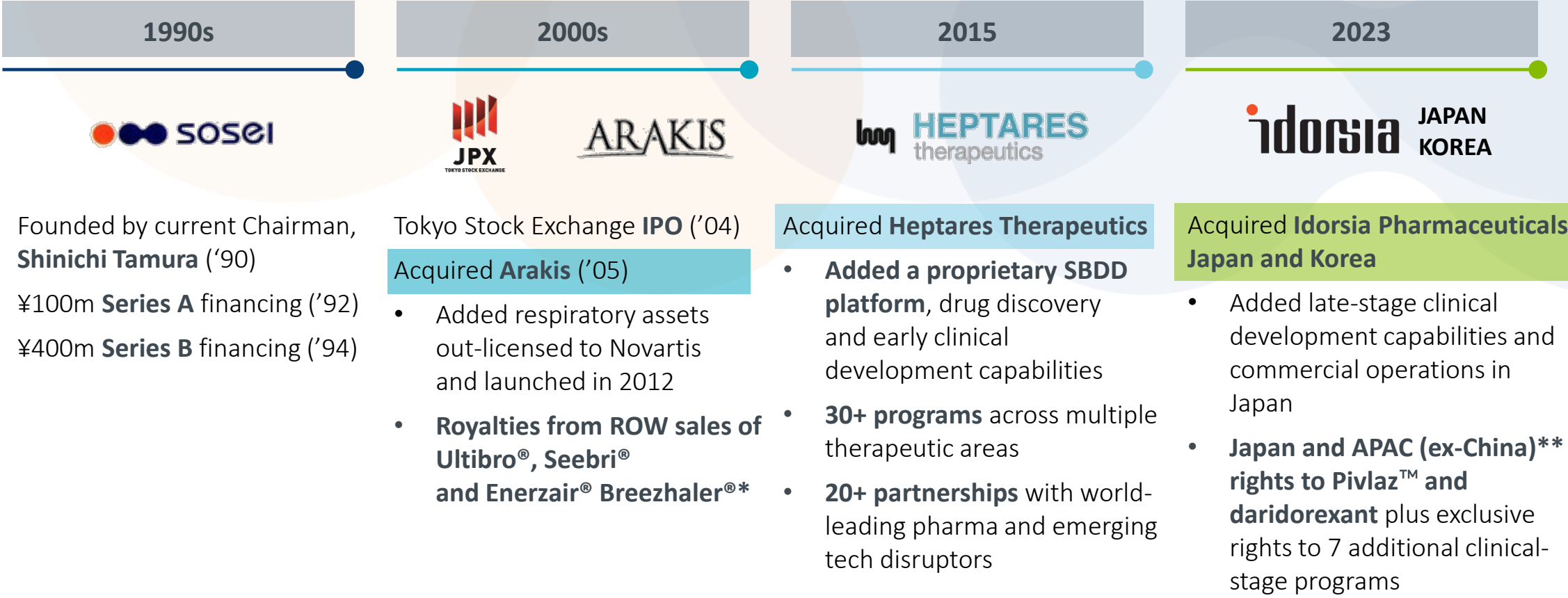
REAL HUMAN OUTCOMES

PROTECTING LIVES EVERYDAY

- **10,300+ PATIENTS** HAVE RECEIVED **PIVLAZ®** (JAPAN AND SHORTLY STH KOREA)
- +4 OTHER PARTNERED MARKETED PRODUCTS

WORLD-CLASS SCIENCE **DELIVERING LIFE-CHANGING MEDICINES**

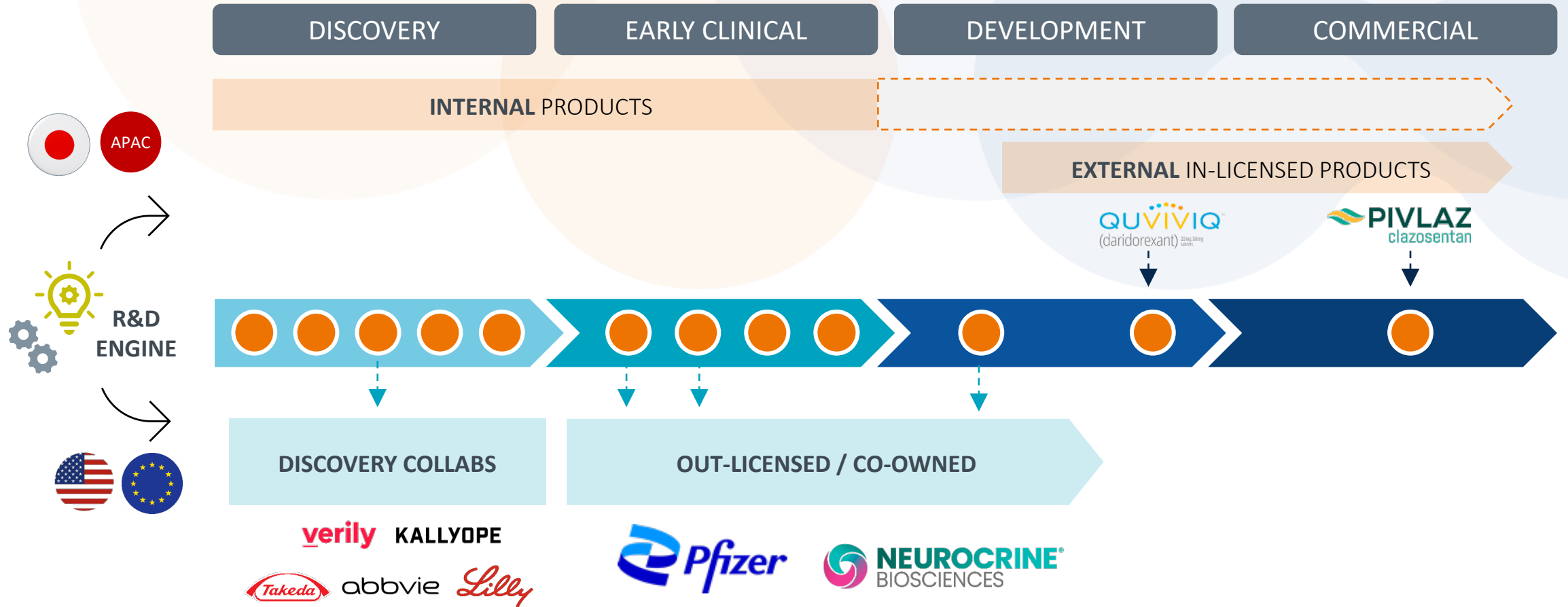
Multiple strategic steps towards an integrated biopharma company



NEW CORPORATE NAME AND BRANDING TO BE LAUNCHED LATE MARCH 2024

Note: *Seebri[®], Ultibro[®], Enerzair[®] and Breezhaler[®] are registered trademarks of Novartis AG.
 **APAC (ex-China) territory includes Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

Core focus on Japan & APAC, global partners for the US/EU5/ROW



DIVERSIFICATION OF A PHARMA COMPANY, WITH THE UPSIDE OF A BIOTECH

2023 in review – a transformative year

CORPORATE MILESTONES

- ✓ Up-listed to **Tokyo Stock Exchange Prime Segment**
- ✓ **Acquisition of Idorsia Pharmaceuticals Japan & APAC (ex-China)**
- ✓ **Landmark investment from Japan Govt JIC VGI fund**

IN-HOUSE DEVELOPMENT

- ✓ **PIVLAZ®** receives **Marketing Approval** in **South Korea**
- ✓ **Japan NDA submission** of **daridorexant** for insomnia
- ✓ HTL'149 (**GPR52 Ag**) entered **Ph 1 trials** for schizophrenia
- ✓ HTL'723 (**EP4 Ant**) entered **Ph 1/2a trials** for advanced solid tumors

PARTNERED PROGRAM PROGRESS

- ✓ **Neurocrine initiates / will initiate Ph 1 trials** of **muscarinic compounds** (M1/M4, M1, M4 agonists) in neuropsychiatry
- ✓ **Pfizer initiates Ph 1** of once daily oral GLP-1 Ag (PF'522)
- ✓ **Temporo Bio receives Ph 1 FDA clearance** of TMP-301 (mGlu5 NAM) for substance abuse

2023 A YEAR OF CORPORATE ACTION AND INVESTMENT FOR FUTURE GROWTH

Our mission – world-leading science, life-changing medicines

CUTTING-EDGE
SCIENCE

PROGRAMS BY
DESIGN

LIFE-CHANGING
MEDICINES

Our first commercially available medicine (PIVLAZ®) is protecting Japanese lives every day



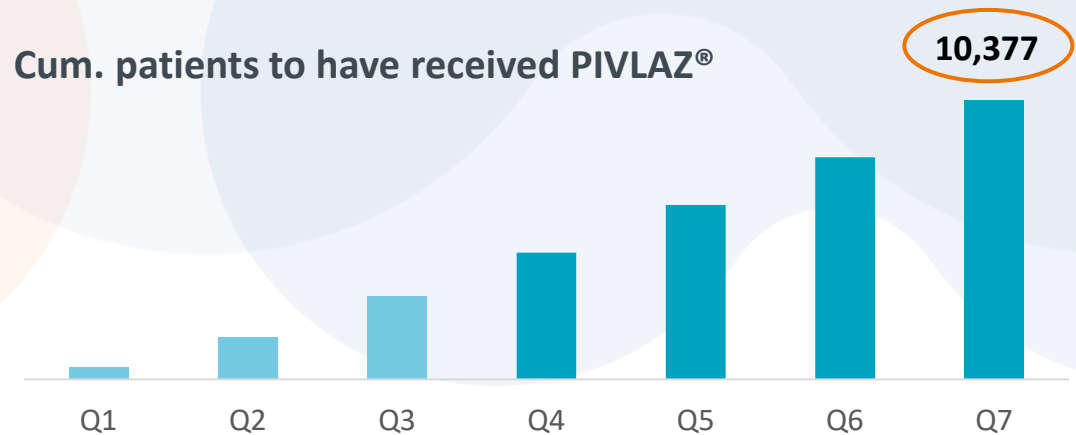
JP GUIDELINES INCLUSION FOR MANAGEMENT OF STROKE¹

- Aug-23: Authorized and recommended by the **Japanese Stroke Society**
- Demonstrated the true endpoints of **Subarachnoid Hemorrhage (SAH)** with higher level of evidence
- Provides confidence to neurosurgeons to **prescribe PIVLAZ® as a new standard of care** for SAH based on strong evidence it can prevent delayed cerebral ischemia and poor outcomes

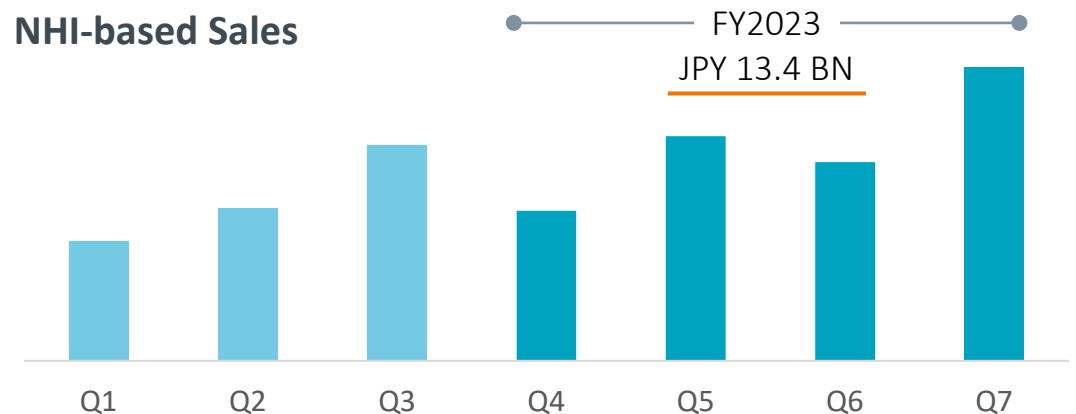
MARKETING APPROVAL FOR SOUTH KOREA

- Dec-23: Received Marketing Approval in South Korea
- Early 2025: Commercially available to patients

Cum. patients to have received PIVLAZ®



NHI-based Sales



PIVLAZ® RAPIDLY BUILDING REAL WORLD EVIDENCE MITIGATING THE RISK OF CEREBRAL VASOSPASM

¹ Japanese Stroke Society Guideline 2021 for the Management of Stroke (Revised Version 2023)

Daridorexant J-NDA filed; expected launch in late 2024 will contribute significantly to Japanese society

QUVIVIQ™
(daridorexant) 25mg, 50mg tablets

Impact of Insomnia on Japanese Society



15 TRILLION YEN (3% GDP)
ECONOMIC LOSS
Due to decreased productivity



604,000
LOST WORKING DAYS / YEAR
Due to absences and sick leave



10%
HIGHER MORTALITY RISK
If average <6 hrs sleep per night

Q4 2024 POTENTIAL LAUNCH IN JAPAN









- Oct-23: J-NDA submitted for the approval of daridorexant, a **dual orexin receptor antagonist**, for the treatment of **adult patients with insomnia**
- NDA includes robust Ph 3 trial data demonstrating **improved Total Sleep Time** and **Latency for Sleep Onset**, while maintaining a **favorable safety profile**
- Daridorexant is marketed in the U.S. and Europe as **QUVIVIQ™** by Idorsia Pharmaceuticals Ltd (Switzerland)
- In Japan, Idorsia Pharmaceuticals Japan and **Mochida Pharmaceutical Co., Ltd** have co-developed and plan to co-market daridorexant pending Japan approval

THE IMPACT OF SLEEP DISORDERS ON JAPANESE SOCIETY IS SIGNIFICANT.
DARIDOREXANT IS A BEST-IN-CLASS SOLUTION FOR INSOMNIA

Source: "Why sleep matters – the economic costs of insufficient sleep" (2016) RAND Research Reports

Clinically exposed to some of the fastest-growing areas of metabolic and neuropsychiatric disorders

PARTNERED PROGRAMS

M ₄ ag 	Schizophrenia Phase 2	GLP-1 ag ✓ 	Metabolic Phase 1
M ₁ M ₄ ag ✓ 	Neuropsychiatry Phase 1	MC4 ant 	Malnutrition Phase 1
M ₄ ag ✓ 	Neuropsychiatry Phase 1	CCR6 ant 	IBD Phase 1
M ₁ ag 	Neuropsychiatry Phase 1-ready	mGlu ₅ NAM ✓ 	Substance abuse Phase 1

IN-HOUSE PROGRAMS

GPR52 ag ✓	Schizophrenia Phase 1
EP4 ant ✓	Solid tumours Phase 1/2a
EP4 ag	IBD Phase 1-ready
GPR35 Ag ¹	IBD Phase 1-ready

✓ Clinical start in 2023

TOGETHER WITH OUR PARTNERS WE ACHIEVED SIX CLINICAL STARTS IN 2023

Note: ¹ Sosei Heptares to regain full ownership of GSK4381406 from GSK ([announced 24-Nov-2023](#))

Our partner Neurocrine has the largest portfolio of muscarinic compounds in development

M4 agonist → Phase 2 → Schizophrenia

- NBI-568 is an investigational, oral, muscarinic M4 selective acetylcholine receptor agonist for the potential treatment of adults with schizophrenia
- Anticipating Phase 2 top-line data in 2H 2024

M1/M4 dual agonist → Phase 1 → Neuropsychiatry

- NBI-570 is an investigational, oral, muscarinic M1/M4 selective dual agonist, studied for the treatment of symptoms of psychosis and cognition in neurological and neuropsychiatric conditions
- Ongoing Phase 1 study

M4 agonist → Phase 1 → Neuropsychiatry

- NBI-569 is an investigational, oral, muscarinic M4-preferring agonist studied for the treatment of neurological and neuropsychiatric conditions
- Ongoing Phase 1 study

M1 agonist → Phase 1-ready → Neuropsychiatry

- NBI-567 is an investigational, oral, muscarinic M1-preferring agonist studied for the treatment of neurological and neuropsychiatric conditions
- Phase 1 study confirmed to be initiated in 2024

MUSCARINIC AGONISM VALIDATED BY KARUNA/KARXT IN SCHIZOPHRENIA

Rapidly advancing in-house programs into the clinic



IMMUNOSUPPRESSION
IN SOLID TUMORS

EP4 ANTAGONIST

- Once daily oral small molecule
- Combination with checkpoint inhibitors
- Collaboration with Cancer Research UK

ONGOING PHASE 1/2A STUDY



- Participants: 150 patients
- Estimated duration: 8/2023 - 9/2026
- No DLTs or SUSARs reported
- Three clinical sites currently open



SCHIZOPHRENIA
AND PSYCHOSIS

GPR52 AGONIST

- Once daily oral small molecule
- 24hr target engagement

ONGOING PHASE 1 STUDY

- Participant: 104 healthy volunteers
- Estimated duration: 6/2023 - 11/2024
- Clinical trial showing good progress through dose escalation



INFLAMMATORY
BOWEL DISEASE

EP4 AGONIST

- Oral GI restricted
- Good potency and selectivity
- Minimal GI systemic exposure

PHASE 1-READY

- Regulatory submission to commence trial completed
- Anticipated Phase 1 start 1H 2024

NEXT WAVE OF POTENTIAL BLOCKBUSTER PROGRAMS ADVANCING INTO THE CLINIC

Note: DLT: Dose Limiting Toxicities, SUSAR: Suspected Unexpected Serious Adverse Reactions

EP4 Ant study link: <https://clinicaltrials.gov/study/NCT05944237?term=Heptares&viewType=Table&page=2&rank=15>

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

Regaining full ownership of GPR35 agonist program from GSK, a genetically validated target



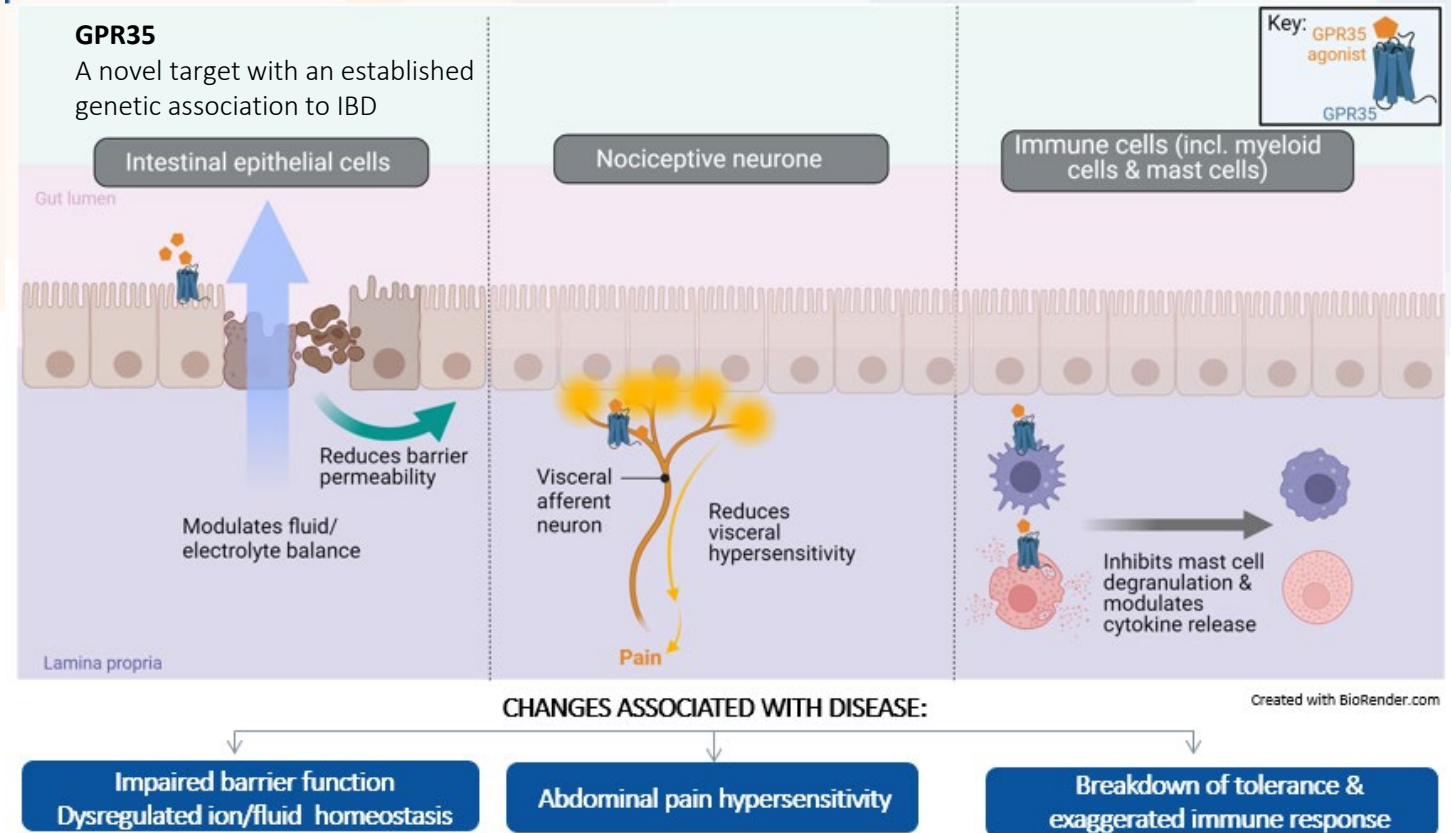
GPR35 AGONIST

- Novel first-in-class, oral GI-restricted GPR35 agonist
- Preclinical data supports potential to improve gut barrier function and reduce visceral pain hypersensitivity

PHASE 1-READY

- GSK had received prior UK MHRA regulatory approval to commence Phase 1 studies¹
- Discontinued by GSK as a result of a reprioritization of its immunology pipeline
- Once regained, intention to initiate Phase 1 study as planned and determine optimal strategy for further clinical development and/or re-partnering

GPR35 AGONIST OFFERS A DIFFERENTIATED MOA TO CURRENT SOC:



SIGNIFICANT UNMET NEED REMAINS IN IBD -
NO EXISTING THERAPIES DIRECTLY ADDRESS BARRIER FUNCTION OR PAIN HYPEREXCITABILITY

Illustration source: GSK

Note: ¹ GPR35 Agonist study link (now withdrawn for strategic business reasons): <https://clinicaltrials.gov/study/NCT05999708?term=GSK4381406&rank=1>

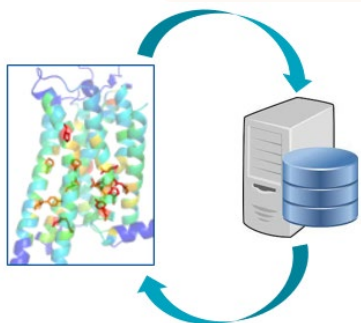
Deep exposure to the high-growth metabolic space



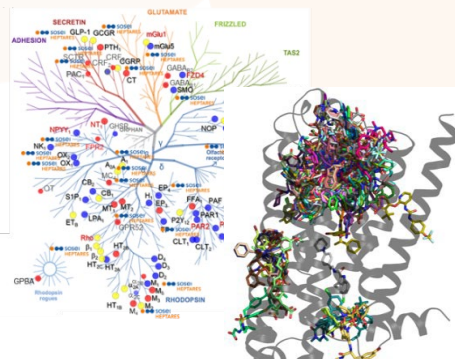
METABOLIC DISEASES - DIABETES AND OBESITY ARE **JUST THE BEGINNING.**
EMERGING RESEARCH SUGGESTS **BENEFITS IN HEART, LIVER AND KIDNEY DISEASES**

Broadly applying AI & ML techniques across our proprietary technology and discovery platform

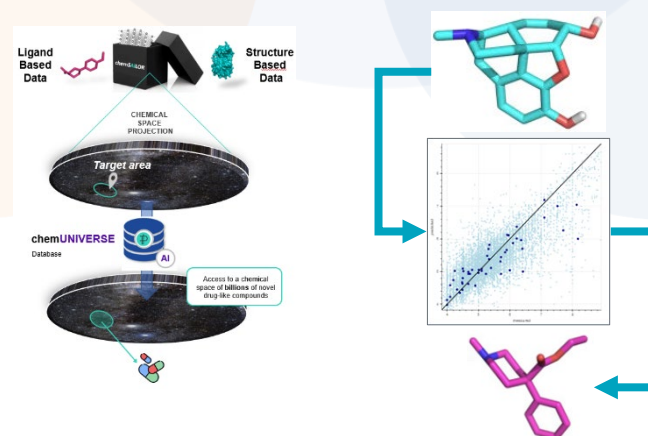
StaR[®] technology



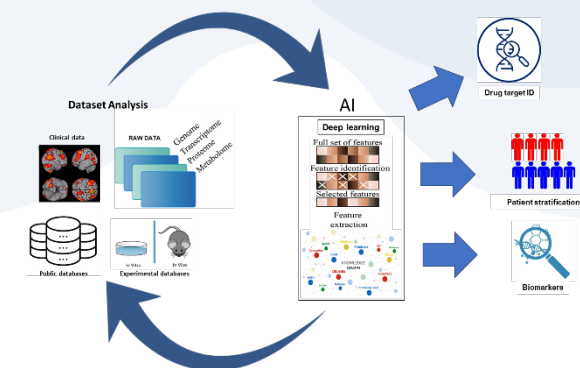
Structure



Molecule Design



Translational Medicine



Approach

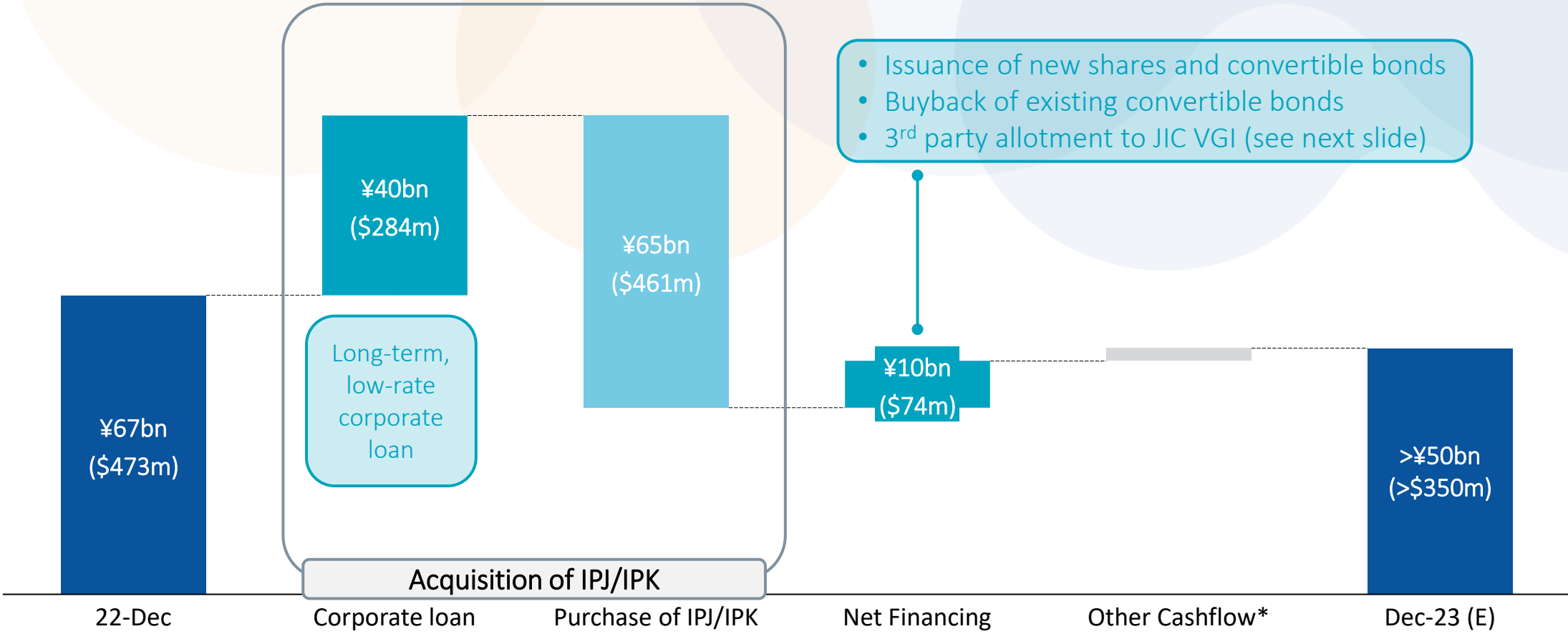
- GPCR rich mutagenesis datasets are mined using ML algorithms to predict future StaR[®] enabling mutations
- AI used to predict GPCR binding site/mode using database of proprietary internal/external structures
- Hit ID through AI-assisted medicinal chemistry expertise
- ML based QSAR models based on proprietary internal and public datasets
- AI led analysis of large patient datasets to identify biomarkers and stratify patients



Impact

- Accelerates StaR[®] generation
- Improves breadth and depth of GPCR homology models to support molecule optimization and virtual screening.
- Supports identification of novel chemical series
- Supports optimization of chemical series to improve drug like properties
- Enables the design of the 'right' clinical studies

Robust cash balance greater than ~¥50bn (\$350m) at year-end



- Issuance of new shares and convertible bonds
- Buyback of existing convertible bonds
- 3rd party allotment to JIC VGI (see next slide)

FINANCIAL CAPACITY TO EXECUTE ON STRATEGIC GROWTH INITIATIVES

IPJ: Idorsia Pharmaceuticals Japan, IPK: Idorsia Pharmaceuticals Korea
 * Illustrative only

Several catalysts on-track to be achieved over the next 12 months

PROGRAM	PARTNER	TIMING	EVENT
Cenerimod	 Idorsia	1H 2024	Exclusive opt-in decision
Lucerastat	 Idorsia	1H 2024	Exclusive opt-in decision
EP4 Ag	 SOSEI HEPTARES	1H 2024	Phase 1 start
Daridorexant (Sth Korea)	 SOSEI HEPTARES	2H 2024	Phase 3 start
Daridorexant (Japan)	 MOCHIDA PHARMACEUTICAL ¹	2H 2024	Approval
PIVLAZ [®] (Sth Korea)	 SOSEI HEPTARES	2H 2024	Launch
GPR35 Ag	 GSK  SOSEI HEPTARES	2H 2024	Program reversion
NBI-568 (M4 Ag)	 NEUROCRINE [®] BIOSCIENCES	2H 2024	Phase 2 completion
NBI-567 (M1 Ag)	 NEUROCRINE [®] BIOSCIENCES	2024	Phase 1 start
TMP-301 (Mglu5 NAM)	 TEMPEROBIO [™]	2024	Phase 2 start
ORX750 (Ox2 Ag)	 CENTESSA PHARMACEUTICALS	2024	Phase 1 start

¹ Co-development and co-promotion agreement with Mochida

Our mission, in progress

CUTTING-EDGE SCIENCE



World-leader in SBDD, utilizing AI/ML tools for **accelerating** drug discovery



Exposure to fastest growing area of healthcare, **revolutionizing** treatments for metabolic diseases

PROGRAMS BY DESIGN



Exclusive opt-ins for Phase 3-ready products, **building** our commitment to healthcare in Japan



Additional pipeline of 30+ medicines by design, **adding** new programs and partners every year

LIFE-CHANGING MEDICINES



PIVLAZ[®] launch ongoing, **protecting** patients daily



Daridorexant NDA filing submitted to PMDA, **transforming** the management of sleep disorders



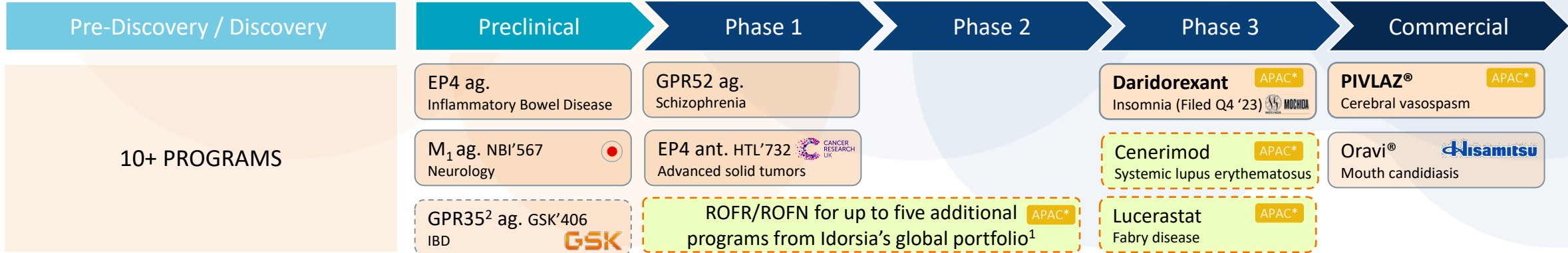
Thank You!

Chris Cargill
Chief Executive Officer

Broad, Diversified and Balanced Pipeline

Pioneering novel and differentiated therapies across multiple therapeutic areas

IN-HOUSE



PARTNERED



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

¹ROFR = Right of First Refusal / ROFN = Right of First Negotiation in the APAC (ex-China) territory for Selatogrel, ACT-1004-1239, ACT-1014-6470, IDOR-1117-2520, ACT-777991

²Sosei Heptares to regain full ownership of GSK4381406 from GSK ([announced 24-Nov-2023](#))

~¥8bn (\$54m) investment from new OPF1 fund of JIC VGI

JIC Venture Growth Investments is an affiliate of govt-backed Japan Investment Corporation (JIC)



**JIC VGI OPPORTUNITY
FUND NO.1 (OPF1)**

INVESTMENT IN SOSEI GROUP CORPORATION

- One of the JIC initiatives included in the **Japan Government's "Startup Development Five-year Plan"**
- Launched in Sept-23 to support the growth and sustainable development of **innovative companies** listed on the Tokyo Stock Exchange
- Engages in **next-generation industries** of significant economic and social benefit to Japan, such as healthcare and life sciences

- JIC VGI has invested in many growth companies in the **healthcare and life sciences sector** and has intrinsic knowledge of biotech companies
- Investment due diligence process conducted over several months, including site visits in the UK and Japan
- Sosei Group Corporation was the **first investment project** from JIC VGI OPF1, accounting for **20% of its total fund size**
- As a **government-supported fund**, OPF1 serves as a **long-term investor**, typically holding investments for 3-5 years on average

OPF1'S INVESTMENT RECOGNIZES THE POSITION OF SOSEI HEPTARES AS AN
EMERGING GLOBAL CHAMPION FOR THE GROWING BIOPHARMACEUTICAL SECTOR IN JAPAN

Locations

SOSEI GROUP

PMO Hanzomon 11F

2-1 Kojimachi,
Chiyoda-ku

Tokyo 102-0083

Japan

Midtown East,

9-7-2 Akasaka Minato-
ku

Tokyo 107-0052

Japan

F17, 410 Teheran-Ro

GangHam-Gu

Seoul 06192

South Korea

Steinmetz Building

Granta Park,

Cambridge CB21 6DG

United Kingdom

North West House

119 Marylebone Road

London NW1 5PU

United Kingdom

VISCHER AG

Aeschenvorstadt 4

4051 Basel

Switzerland