

# H1 FY2017 Financial results and corporate update

9 November 2017

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## Agenda

**1**

### **Highlights**

Peter Bains, CEO

**2**

### **H1 FY2017 Financial Results**

Andrew Oakley, CFO

**3**

### **Strategic and Operational Update**

Peter Bains, CEO

**4**

### **Q&A**

## Significant strategic and operational progress across multiple fronts

- Partnered GPCR pipeline developing well, with zero clinical attrition to date – further validates our Structure-based Drug Design (SBDD) approach
- Multiple development milestones received (Allergan M<sub>4</sub>, Teva CGRP, AstraZeneca A<sub>2A</sub>) – evidence of our partners' progress
- Entered high potential field of RNA Therapeutics with strategic investment in MiNA – Boehringer Ingelheim deal supports the promising potential of MiNA's saRNA technology
- Integration of G7 Therapeutics complete, now Heptares Zurich – modest investment has significantly increased our annual StaR® GPCR structure output
- Investment in StaR® technology driving Proprietary pipeline progress – Up to 3 novel drug candidates to enter Phase 1 every year commencing CY2018
- Heptares Co-founder Dr. Richard Henderson awarded 2017 Nobel Prize for Chemistry – Cryo-EM knowledge now being applied to our SBDD approach
- Amendment to global agreement with Allergan for commercial rights to M<sub>1</sub> for DLB in Japan – first go-to-market opportunity in area of significant unmet medical need

**StaR® and SBDD is consolidating our position as the world leader in GPCR medicine discovery and design – we are building Japan's first global biotech champion**

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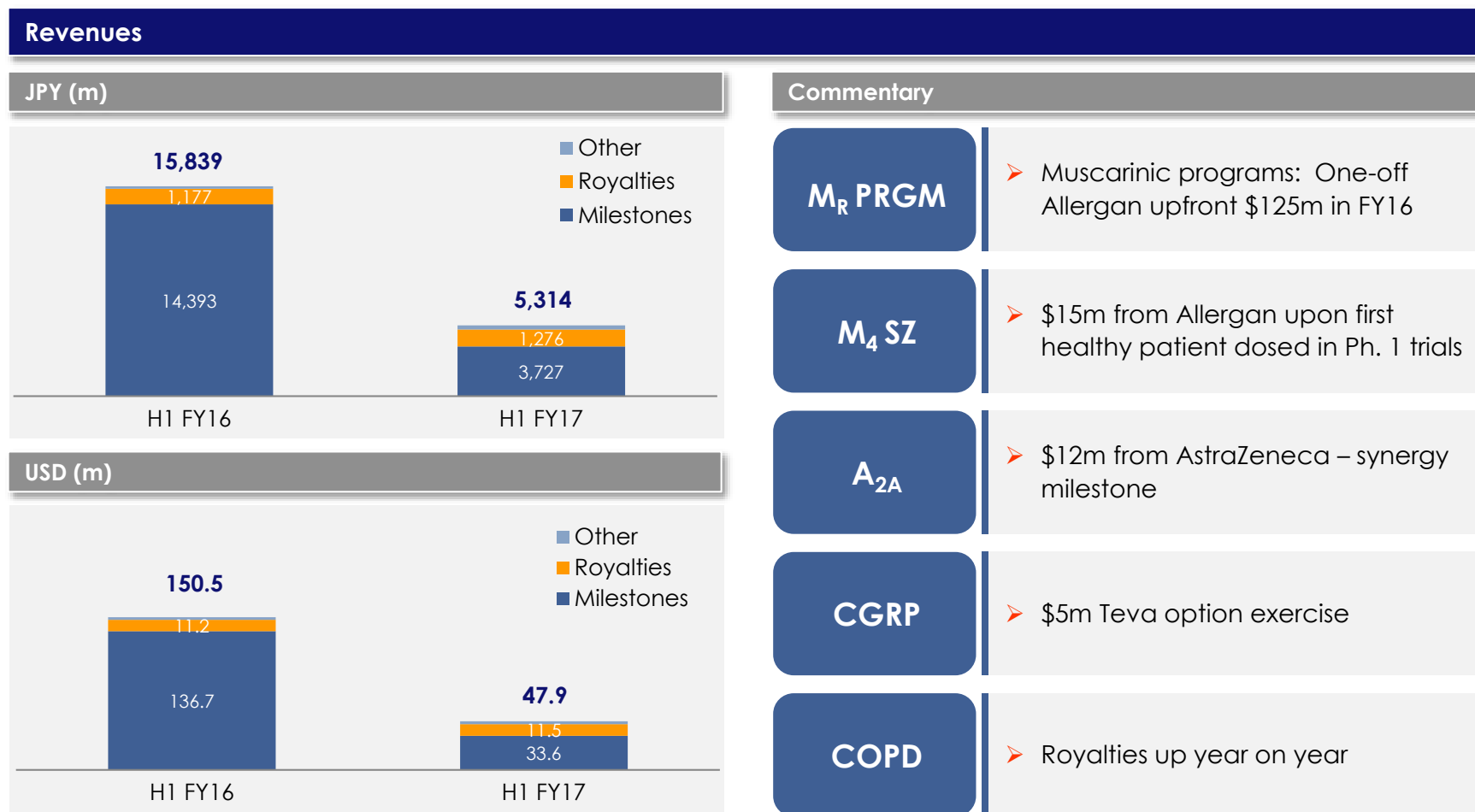
### Strategic and Operational Update

Peter Bains, CEO

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### Q&A

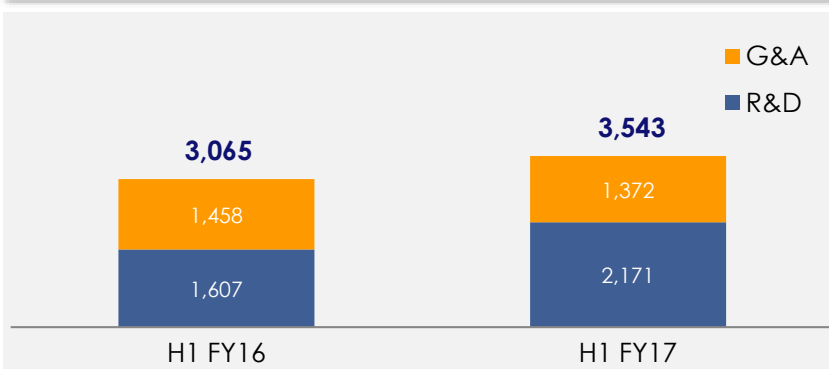
## Allergan upfront milestone in FY16 drives variance



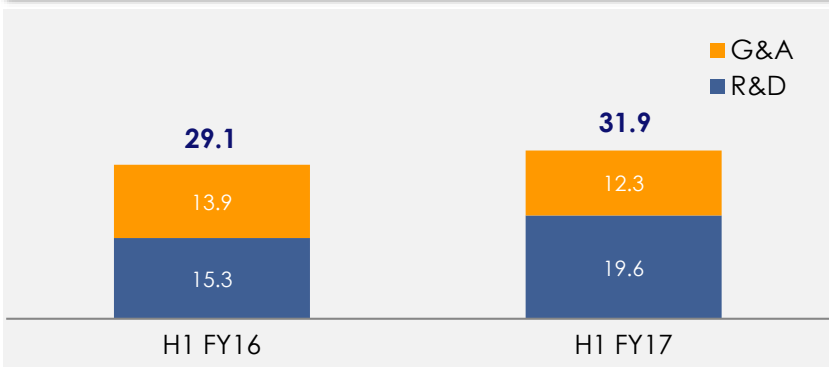
## Cash Operating Expenditure linked to investments to advance and support progress across the Proprietary GPCR pipeline

### Cash Operating Expenditure

#### JPY (m)



#### USD (m)



#### Commentary

##### R&D

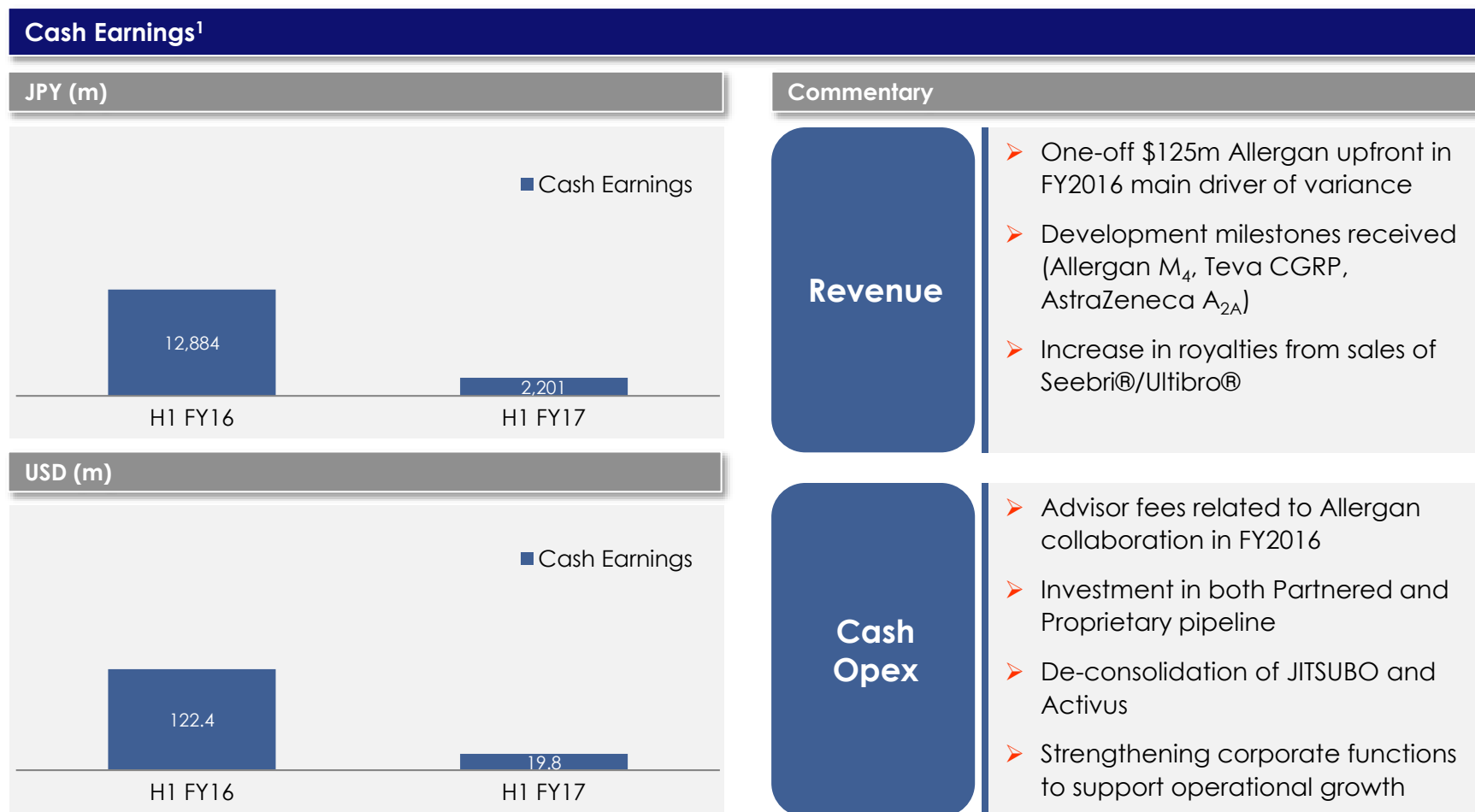
- Ongoing investment in Partnered programs to develop back-up/follow-up molecules
- Investment behind Proprietary GPCR pipeline
- Start-up costs related to DLB (Japan) program
- Deconsolidation of JITSUBO and Activus

##### G&A

- Advisor fee in FY2016 for Allergan collaboration
- Strengthening corporate functions to support operational growth
- Several key positions filled



# Cash Earnings<sup>1</sup>



<sup>1</sup> Cash Earnings = Revenues – Cash Operating Expenditure



## Allergan upfront milestone in FY2016 drives variance

### Summary Income Statement

	JPY		USD		Commentary
	H1 FY17 JPY mm	H1 FY16 JPY mm	H1 FY17 USD mm	H1 FY16 USD mm	
Sep-17					
Revenue	5,314	15,839	47.9	150.5	
Other Income	429	110	3.9	1.0	
Cash Opex	3,543	3,065	31.9	29.1	
<b>Cash Earnings<sup>1</sup></b>	<b>2,201</b>	<b>12,884</b>	<b>19.8</b>	<b>122.4</b>	
Non Cash Costs	757	661	6.8	6.3	
Fin, FX & Cont. Consid.	1,743	(1,023)	15.7	(9.7)	
Equity Results & MI	235	(124)	2.1	(1.2)	
Tax Expense	(37)	2,653	(0.3)	25.2	
<b>Net Income</b>	<b>(498)</b>	<b>10,717</b>	<b>(4.5)</b>	<b>101.8</b>	

- Non-cash costs: increase in amortization of intangibles due to acquisition of G7 Therapeutics and stock comp
- FX: Losses in FY2017 vs. Brexit-related gains in FY2016
- Contingent consideration:
  - Represents additional purchase consideration related to Heptares
  - Charge related to \$125m Allergan upfront included in FY2015
  - Annual charge is an accounting based methodology - not in line with underlying business performance
- Tax charge (benefit) driven by UK tax position

**We are continuing to invest and scale which is driving significant progress across the pipeline**

<sup>1</sup> Cash Earnings = Revenues – Cash Operating Expenditure

## Guidance for FY2017 (March 2018)

### Revenue

- “Biotech business model” – milestone dependent, timing difficult to predict with certainty
- Ultifbron™ Neohaler® & Seebri™ Neohaler® now both launched in the United States<sup>1</sup>

### Cash Opex

- R&D Cash Opex: USD 50 to 55 million (JPY 5.6 to 6.2 billion)
- G&A Cash Opex: USD 20 to 25 million (JPY 2.3 to 2.8 billion)

### Cash Earnings<sup>2</sup>

- Cash Earnings<sup>2</sup> performance expected to be around breakeven for FY2017

**Risk-balanced capital allocation framework will drive long term growth and value creation.  
Company to change its year end to December effective December 2018**

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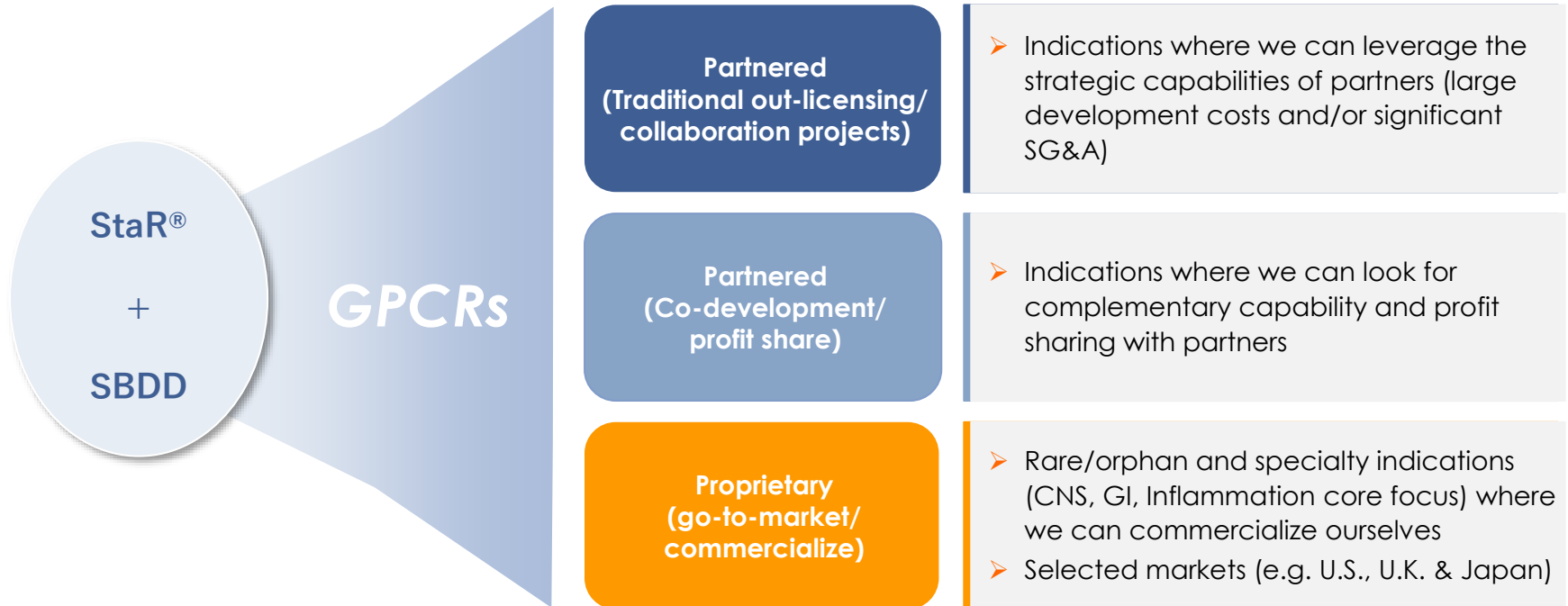
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### Q&A

## Risk-balanced capital allocation framework

*Optimizes value capture*



Reserving the right to choose which strategy is most appropriate for each drug candidate, with a goal to increasingly commercialize ourselves in selected indications and markets

## Sosei to advance clinical development in Japan of HTL0018318 in patients with dementia with Lewy Bodies (DLB)

### Amendment to our 2016 global R&D and commercialization partnership with Allergan

- Amendment sees Sosei gain a license to develop and commercialize HTL0018318, a novel muscarinic M<sub>1</sub> receptor agonist, in Japan as a potential new treatment for patients with dementia with Lewy bodies (DLB)
- Initially, Sosei will undertake a Phase 2 proof-of-concept monotherapy study, expected to begin in Japan in 2018
  - Intention to advance HTL0018318 through Phase 2b/3, registration and onto the market in Japan
- Enables HTL0018318 clinical programs to run in parallel in dementia patients in AD and in DLB
- DLB is the second largest dementia population after AD, and a major healthcare issue globally
- Strong go-to-market opportunity for M<sub>1</sub> program in Japan
  - Leverages our expertise in DLB clinical capabilities, and broader track record of successful product development in Japan
  - Satisfies a key element of growth strategy – manageable indication treated in specialist centres, with sizeable market opportunity to build and retain more value for shareholders
- Allergan has retained the right to development HTL0018318 in DLB globally

**Strong go-to-market opportunity for our lead M<sub>1</sub> program in Japan which is consistent with our growth strategy, and demonstrates our commitment to tackling a major Japanese health issue (dementia)**

# What is dementia with Lewy Bodies (DLB)?

Significant unmet need for new therapeutic approach

## Overview of DLB

- Dementia with Lewy Bodies (DLB) is the second most prevalent cause of dementia in elderly patients, and one of three major types of dementia
- Progressive neurodegenerative dementia characterized by significant cognitive fluctuations, distressing neuropsychiatric symptoms (e.g. visual hallucinations), and parkinsonism
- Recent advances in DLB diagnosis have increased awareness and opportunity to evaluate new treatments – in part due to approval of Aricept® for DLB and activities of Eisai to develop specialist centres
- Dementia is a social and 'political' priority in Japan

### Patient population

- Up to 920,000 in Japan (c.20%<sup>1</sup> of 4.6 million<sup>2</sup> currently living with dementia)
- Sizeable DLB population in the US<sup>3</sup>

### Significant unmet need

- Aricept® only conditionally approved in Japan for the treatment of DLB in 2014<sup>4</sup>
- No drugs approved in the US or EU

### Cholinergic deficits

- Cholinergic deficits a prominent feature of DLB patients
- Cholinergic neurotransmission more dysfunctional in DLB than AD

## Potential Muscarinic M<sub>1</sub> agonist for DLB

- Post-synaptic neurons (and muscarinic M<sub>1</sub> receptors) preserved in DLB
- Direct post-synaptic activation via M<sub>1</sub> receptors is independent of acetylcholine levels which decline as disease progresses
- An M<sub>1</sub> agonist that directly stimulates post-synaptic receptors would offer broad therapeutic potential in treatment of neurodegenerative conditions such as DLB

<sup>1</sup> Eisai press release, April 2015

<sup>2</sup> <https://www.alz.org/jp/dementia-alzheimers-japan.asp>

<sup>3</sup> <https://www.lbda.org/content/incidence-lewy-body-dementias-general-population>

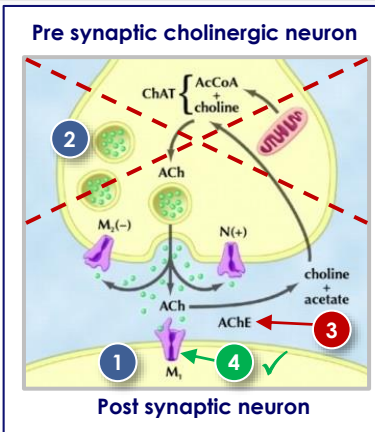
<sup>4</sup> Japan PDMA review process ongoing

# HTL0018318 is a potential first-in-class therapy for DLB

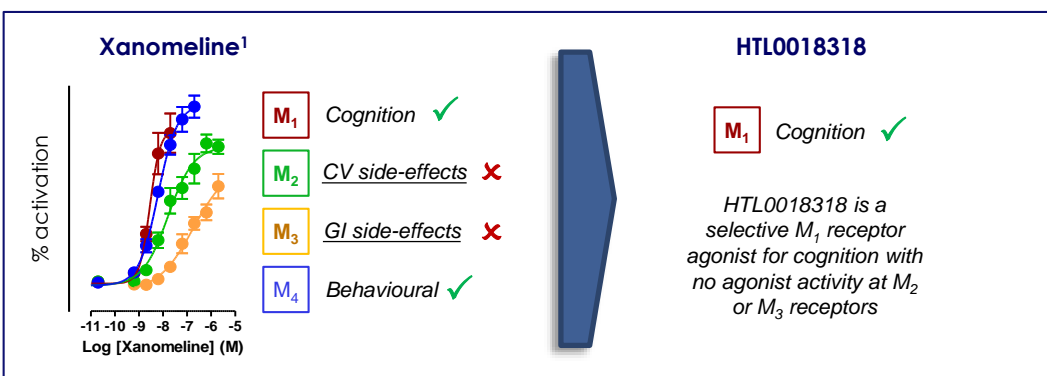
## A selective M<sub>1</sub> agonist

### Overview of the HTL0018318 muscarinic M<sub>1</sub> receptor agonist approach for DLB

- Cognitive benefits of M<sub>1</sub> agonist supported by clinical studies of xanomeline<sup>1</sup>
- However, xanomeline clinical development stopped due to unacceptable CV and GI side effects linked to stimulation of M<sub>2</sub> & M<sub>3</sub>
- StaR® & SBDD to “design out” unwanted selectivity over the M<sub>2</sub> & M<sub>3</sub> receptors
- HTL0018318 is a potent muscarinic M<sub>1</sub> agonist with limited M<sub>2</sub>/M<sub>3</sub> agonism



- 1 M<sub>1</sub> receptors in cortex and hippocampus are key in mediating cognitive effects of acetylcholine (ACh)
- 2 The loss of cholinergic neurons in dementia patients leads to decline in cognitive functions
- 3 Acetyl-cholinesterase (AChE) inhibitors (e.g. Aricept®) prevent the breakdown of ACh
  - Effects are limited however, due to dose-limiting side-effects and the loss of endogenous ACh levels as the disease progresses
- 4 M<sub>1</sub> agonist activates receptor independently of ACh levels
  - HTL0018318 derived from StaR® and SBDD, potentially driving comparable pre-clinical effects and a potentially differentiated profile to Aricept®


















HTL0018318 has a differentiated mechanism of action with the potential to optimise symptomatic benefits in DLB patients

Source: Internal analysis

<sup>1</sup> Bodick et. al. "Effects of Xanomeline, a Selective Muscarinic Receptor Agonist, on Cognitive Function and Behavioural Symptoms in Alzheimer's Disease" Arch Neurol. 1997;54@465-473



## Significant progress across partnered programs and collaborations

Program	Partner	TA	Indication	Progress last 6 months	
Partnered programs and collaborations					
NEW M <sub>1</sub> AD	 Allergan	CNS	Alzheimer's disease	<ul style="list-style-type: none"> <li>Start of new Ph 1b clinical trial with selective M<sub>1</sub> agonist</li> <li>HTL0018318 selected based on its superior profile</li> </ul>	
H1 17 M <sub>4</sub> SZ	 Allergan	CNS	Neurobehavioral symptoms of Alzheimer's disease	<ul style="list-style-type: none"> <li>First healthy subject dosed with the first-in-class, selective M<sub>4</sub> agonist HTL0016878 in a Phase 1 clinical study</li> <li>US\$15m milestone payment triggered</li> </ul>	
NEW A <sub>2A</sub>	 AstraZeneca	ONC	Immuno-oncology Mult. tumor types	<ul style="list-style-type: none"> <li>AZD4635 Ph 1 trial progressing to signal seeking Ph 1b studies by year end CY2017<sup>1</sup></li> <li>Currently in a Ph. 1 clinical trial as a single agent and in combination with AstraZeneca's IMFINZI™ (durvalumab)</li> </ul>	
H1 17 CGRP	 TEVA	CNS	Migraine	<ul style="list-style-type: none"> <li>Candidate nominated in 2Q17 is in preclinical with the aim of taking it into Ph. 1 clinical studies at the earliest opportunity – emerged from rigorous selection process</li> </ul>	
NEW 	 Pfizer		Mult. Targets (SME/mAb)	<ul style="list-style-type: none"> <li>11 pre-clinical milestones delivered to Pfizer (including StaR®, X-ray structures, and lead molecules), plus new intellectual property generated</li> </ul>	
NEW 	 MiNA Therapeutics  Boehringer Ingelheim	LIVER	Mult. Targets (saRNA) Fibrotic Liver Diseases	<ul style="list-style-type: none"> <li>MiNA<sup>2</sup> deal with BI to develop novel treatment approaches for fibrotic liver diseases</li> <li>Upfront, R&amp;D funding, plus milestones up to EUR 307m<sup>3</sup></li> </ul>	





<sup>1</sup> Signal seeking phase 1b expansion cohorts in a number of tumor types with monotherapy and/or in combination with IMFINZI™ are planned to open by end CY2017

<sup>2</sup> MiNA is 25.6% owned by Sosei

<sup>3</sup> MiNA also entitled to double-digit royalties on sales of selected products resulting from the partnership

## Proprietary programs now led by M<sub>1</sub> DLB opportunity in Japan

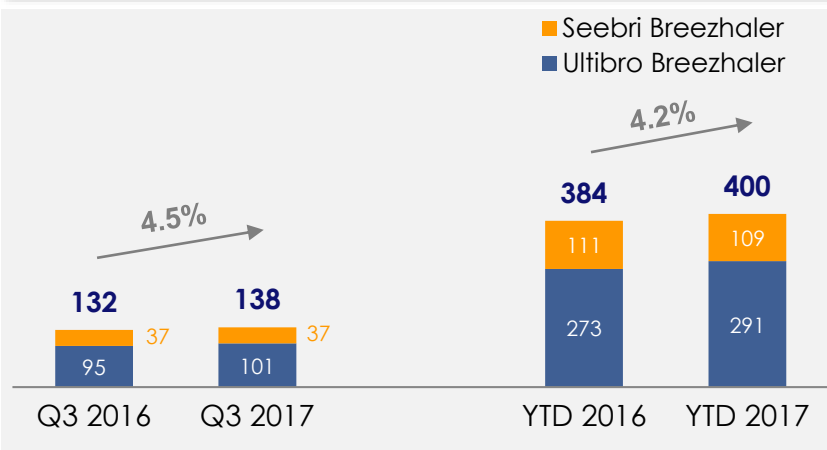
*Focus on selected rare/orphan and specialty indications or markets*

Program	Partner	TA	Indication	Progress last 6 months
Proprietary programs				
NEW <b>M<sub>1</sub> DLB</b>		CNS	Dementia with Lewy Bodies (Japan)	<ul style="list-style-type: none"> <li>➤ <u>License to develop and commercialize HTL0018318 for DLB in Japan</u> – a novel muscarinic M<sub>1</sub> receptor agonist</li> <li>➤ <u>Ph. 2a POC monotherapy study starting CY2018</u></li> <li>➤ Intention to advance HTL0018318 through Ph.2b/3, and registration and onto the market in Japan</li> </ul> 
NEW <b>mGlu<sub>5</sub></b>		CNS	Neurological diseases	<ul style="list-style-type: none"> <li>➤ Preclinical work progressing well, potential best-in-class mGlu<sub>5</sub> NAM for CNS diseases</li> <li>➤ 10-fold more potent than the most advanced clinical agent</li> <li>➤ Mechanism validated in multiple CNS areas of high unmet need</li> <li>➤ <u>Ph. 1 clinical studies starting CY2018</u></li> </ul> 

## Strong and growing royalty from respiratory disease products Seebri®/Ultibro®

### Novartis's reported product sales Q3 & YTD (ex-US)

USD (mm)



### Commentary<sup>1</sup>

- In Q3, Ultibro® remained the leading LAMA/LABA with more than 50% of total class share (ex-US)
- Total reported Q3 net sales for Ultibro® grew 6%, impacted by short term normalization of stocking effects in certain territories outside Europe
- In Europe, which accounts for majority of reported net sales, Ultibro® grew +18% year-on-year despite increased competition, underpinned by notable performances in Germany and France
- Recent launches of Utibron™ and Seebri™ in the US by Sunovion may provide further upside

Product/Program	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Market
<b>Other Medicines Partnered Pipeline (Traditional out-licensing)</b>								
Seebri®/Ultibro®	COPD	NOVARTIS						
QVM 149	Asthma	NOVARTIS						

**Ultibro® remains the leading LAMA/LABA with more than 50% of total class share (ex-US), with notable strong performance in Europe. Recent US<sup>2</sup> launches by Sunovion provide further upside**

<sup>1</sup> Publicly available disclosures

<sup>2</sup> Marketed in the U.S. as Seebri™ Neohaler® and Utibron™ Neohaler® by Novartis' commercialisation partner Sunovion

# MiNA<sup>1</sup> agreement with BI further supports the potential for saRNA

## Leading position in saRNA

- Demonstrates MiNA's leading position in saRNA therapeutics
- MiNA's lead saRNA candidate, CEBPA, currently in Ph. 1/2a clinical studies

## Validates the technology

- Validates the saRNA technology, and enables the potential acceleration of the platform, which represents significant potential upside for Sosei

## Expands capability, capacity and pipeline

- Enables MiNA to build-up capability (and capacity) ahead of any future decision regarding our strategic investment

## Additional source of diversified non-dilutive financing

- Upfront payment, committed R&D funding plus potential research, development and regulatory milestone payments up to EUR 307 million
- Double-digit royalties on sales of selected products from the partnership

Product/Program	Modality	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Market
<b>Partnered saRNA Pipeline (Traditional out-licensing)</b>									
Multiple targets	saRNA	Multiple							
<b>Proprietary saRNA Pipeline (Go-to-market/commercialize)</b>									
MTL-CEBPA	saRNA	Liver cancer							
MTL-CEBPA	saRNA	Multiple							
MTL-Other	saRNA	Multiple							

: Current stage  
 : Next 12-15 mths progress

MiNA is collaborating with Boehringer Ingelheim, a world-leader in fibrotic liver diseases, to develop expertise in chronic administration, in addition to its potential acute treatment CEBPA for liver cancer

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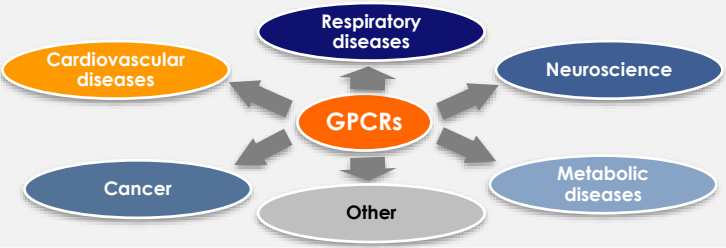
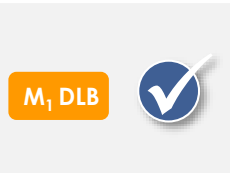


Peter Bains, CEO

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### **Q&A – Thank you!**

# Appendix

## Building Japan's first global biotech champion

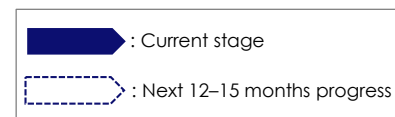
<p><b>World-leader in GPCRs</b></p>	<ul style="list-style-type: none"> <li>➤ Exploiting the vast untapped opportunity to design drugs that target GPCRs</li> </ul>	
<p><b>Patent-protected StaR® &amp; SBDD platform</b></p>	<ul style="list-style-type: none"> <li>➤ Unique, scalable patent-protected StaR® technology building a deep pipeline with potential for lower attrition due to SBDD approach</li> </ul>	
<p><b>Risk-balanced capital allocation framework</b></p>	<ul style="list-style-type: none"> <li>➤ Strategically advancing to include greater focus on go-to-market/profit share opportunities in selected indications (e.g. rare/orphan and specialty) and markets (US, UK, Japan)</li> </ul>	
<p><b>Pharma partnerships in multiple therapeutic areas</b></p>	<ul style="list-style-type: none"> <li>➤ Partnered GPCR pipeline in neurology, immuno-oncology, CNS &amp; other diseases – validates technology</li> <li>➤ c.\$6bn in potential development, regulatory &amp; commercial milestones to come, plus royalties on sales</li> </ul>	
<p><b>Emerging proprietary GPCR pipeline</b></p>	<ul style="list-style-type: none"> <li>➤ Accelerate our Proprietary GPCR pipeline into clinical development and through to commercialization, with ability to enter up to 3 novel candidates into Ph. 1 every year</li> </ul>	













Plus continued growth from legacy Seebri®/Ultibro® royalties and our strategic investment in the exciting field of RNA Therapeutics with MiNA



# World leader in GPCR medicines

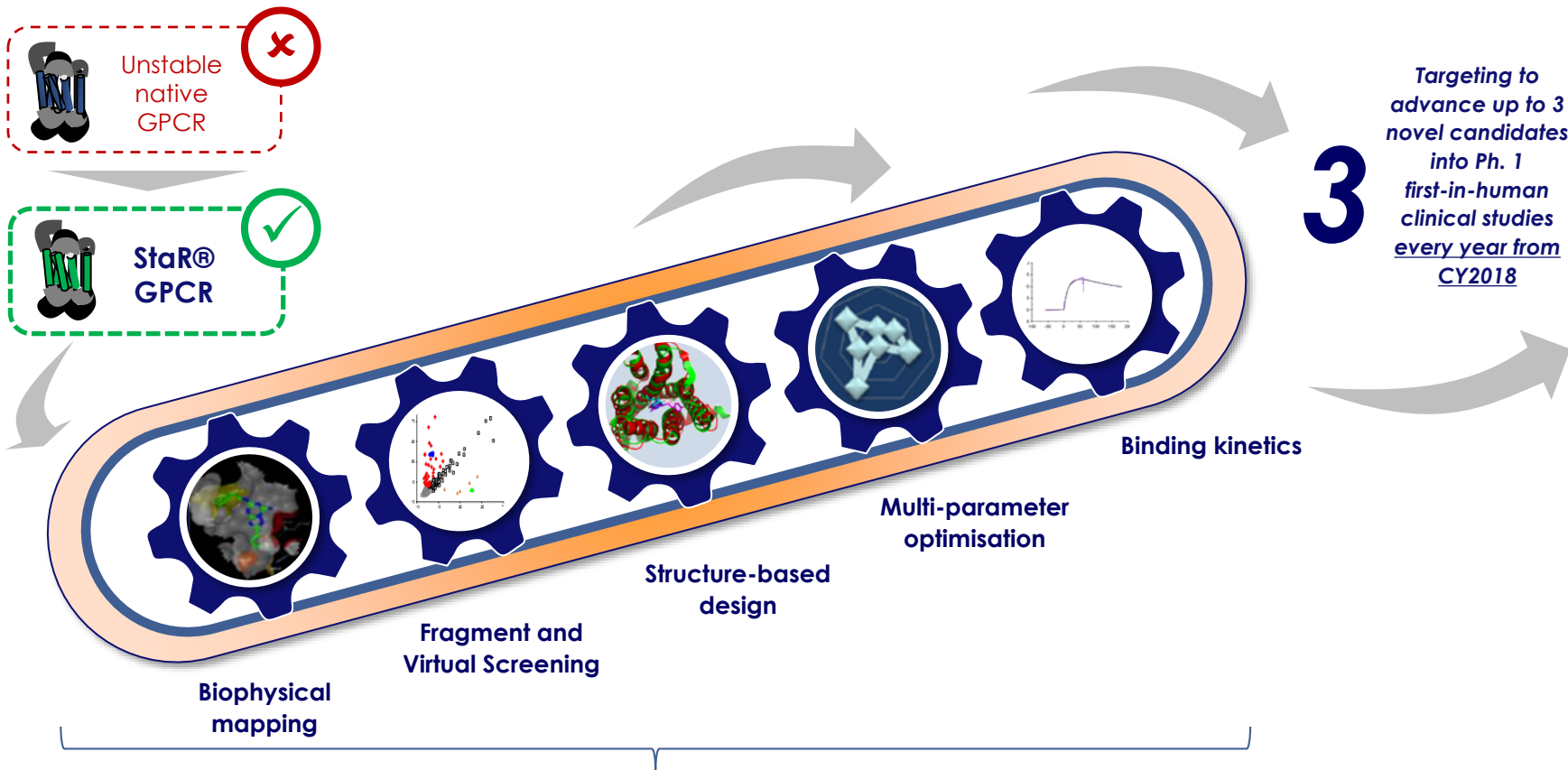
## Balanced and diversified pipeline



Product/Program	Modality	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Market	
<b>Partnered Pipeline - Legacy Respiratory Products (Traditional out-licensing)</b>										
Seebri®/Ultibro®	SME	COPD	 NOVARTIS	<span style="color: blue;">▬</span>						
QVM149	SME	COPD	 NOVARTIS	<span style="color: blue;">▬</span>						
<b>Partnered GPCR Pipeline (Traditional out-licensing/collaboration projects) – formerly known as “Wave 1”</b>										
M <sub>1</sub> agonist	SME	AD/Sz Cognition	 Allergan	<span style="color: blue;">▬</span>						
M <sub>4</sub> agonist	SME	AD/Sz Psychosis	 Allergan	<span style="color: blue;">▬</span>						
M <sub>1</sub> /M <sub>4</sub> dual agonist	SME	AD/Sz Psych. /Cog.	 Allergan	<span style="color: blue;">▬</span>						
A <sub>2A</sub> antagonist	SME	Cancer I/O	 AstraZeneca	<span style="color: blue;">▬</span>						
CGRP antagonist	SME	Migraine	 TEVA	<span style="color: blue;">▬</span>						
Not disclosed	SME	Pain	 Daiichi-Sankyo	<span style="color: blue;">▬</span>						
Multiple targets	SME/mAb	Multiple indications	 Pfizer	<span style="color: blue;">▬</span>						
Not disclosed	SME	Not disclosed	 morphosys	<span style="color: blue;">▬</span>						
<b>Partnered GPCR Pipeline (Co-development/profit share)</b>										
Not disclosed	PEP	Inflammation	 Psaltrinam	<span style="color: blue;">▬</span>						
Multiple targets	mAb	Immuno-oncology	 kymab	<span style="color: blue;">▬</span>						
<b>Proprietary GPCR Pipeline (Go-to-market/commercialize) - formerly known as “Wave 2”</b>										
M <sub>1</sub> agonist	SME	DLB (Japan)		<span style="color: blue;">▬</span>						
mGlu <sub>5</sub> NAM	SME	CNS		<span style="color: blue;">▬</span>						
Molecule 1	SME	Undisclosed		<span style="color: blue;">▬</span>						
Molecule 2	SME	Undisclosed		<span style="color: blue;">▬</span>						
Molecule 3	SME	Undisclosed		<span style="color: blue;">▬</span>						
Molecule 4	SME	Undisclosed		<span style="color: blue;">▬</span>						
Molecule 5	SME	Undisclosed		<span style="color: blue;">▬</span>						

# SBDD underpinned by StaR® enables us to build a deep pipeline

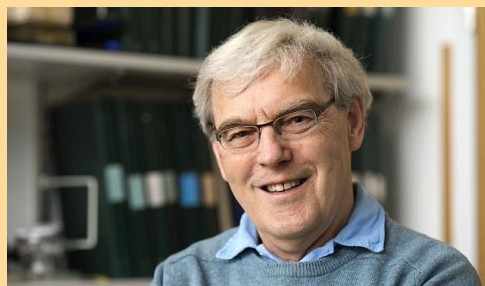
*Unique and scalable platform*



**Structure-Based Drug Design (SBDD) engine** – Multiple High Quality Chemotypes

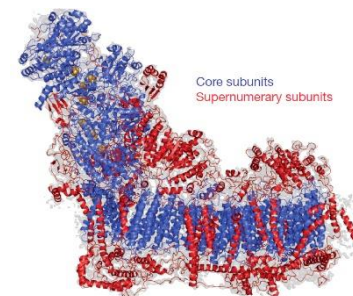
Our proprietary StaR® GPCR technology allows us to utilize a variety of SBDD approaches. Up to 3 novel drug candidates entering Ph. 1 clinical studies every year from CY2018

## Message from Dr. Richard Henderson 2017 Nobel Prize winner in Chemistry



### Dr. Richard Henderson

- Born 1945 in Edinburgh, Scotland.
- Ph.D. 1969, Cambridge University, UK.
- Programme Leader, MRC Laboratory of Molecular Biology, Cambridge, UK
- Co-founder of Heptares Therapeutics
- Scientific Advisor to Sosei/Heptares

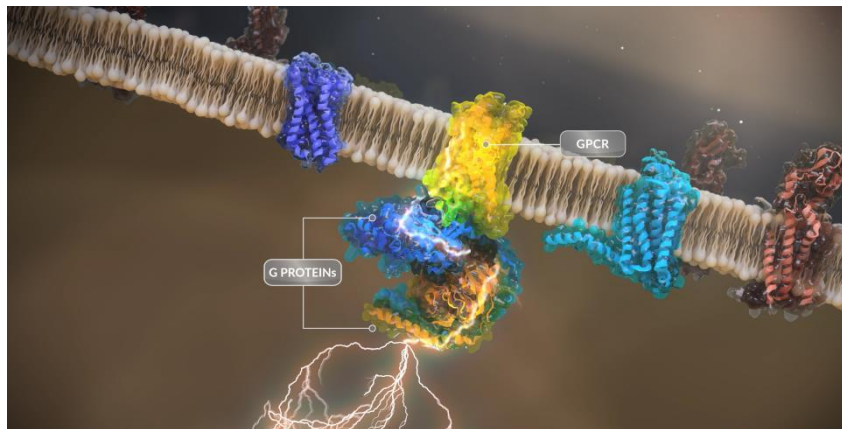


*"I am proud to have co-founded Sosei's subsidiary Heptares where I continue to act as a scientific advisor to the company – a leader in GPCR medicine design and development. My work in the area of cryo-EM, for which I was jointly awarded the 2017 Nobel Prize in Chemistry, is a pioneering area of structural biology. Cryo-EM can reveal the structure of complex molecular assemblies to near atomic level. Together with the MRC Laboratory, where I am programme leader, Heptares is applying the techniques of cryo-EM to advance the discovery of new GPCR medicines. I look forward to speaking to Sosei shareholders in March 2018."*

*– Dr. Richard Henderson, Co-founder of Sosei's subsidiary Heptares Therapeutics*

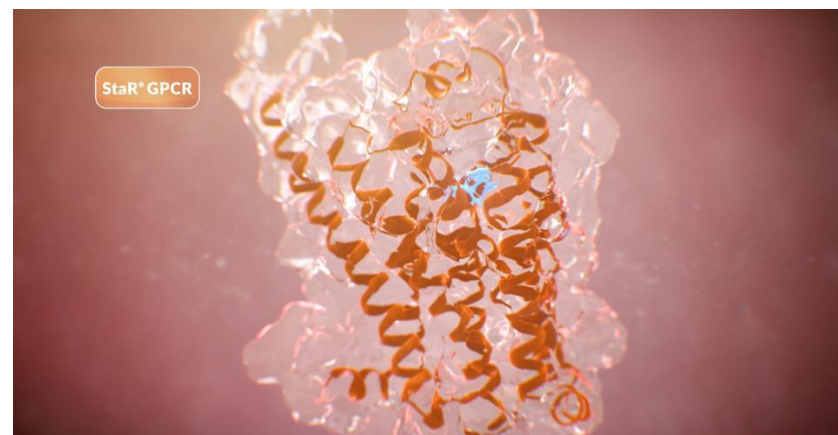
**Special Nobel Prize honorary event for Sosei shareholders in March 2018 in Tokyo with Dr. Richard Henderson as keynote speaker. More details in early 2018 – see IR website**

Check out our new StaR® GPCR & SBDD video!



**English link:**

[https://www.youtube.com/watch?v=3lcoweP\\_z4M](https://www.youtube.com/watch?v=3lcoweP_z4M)



**日本語 (Japanese) link:**

<https://www.youtube.com/watch?v=E4KCDIzfdzg>

StaR® GPCRs and SBDD is consolidating our position as the world leader in GPCR medicine discovery, design and development – we are building Japan's global biotech champion