

# **1H 2016 Results Conference Call**

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**[www.osei.com](http://www.osei.com)**

# Agenda

**1. Financial Highlights (Q2 FY2016)**

**2. Business Highlights (Q2 FY2016)**

**3. Mid to Long term Strategy**

**4. Q&A**

# 1. Financial Highlights (Q2 FY2016)

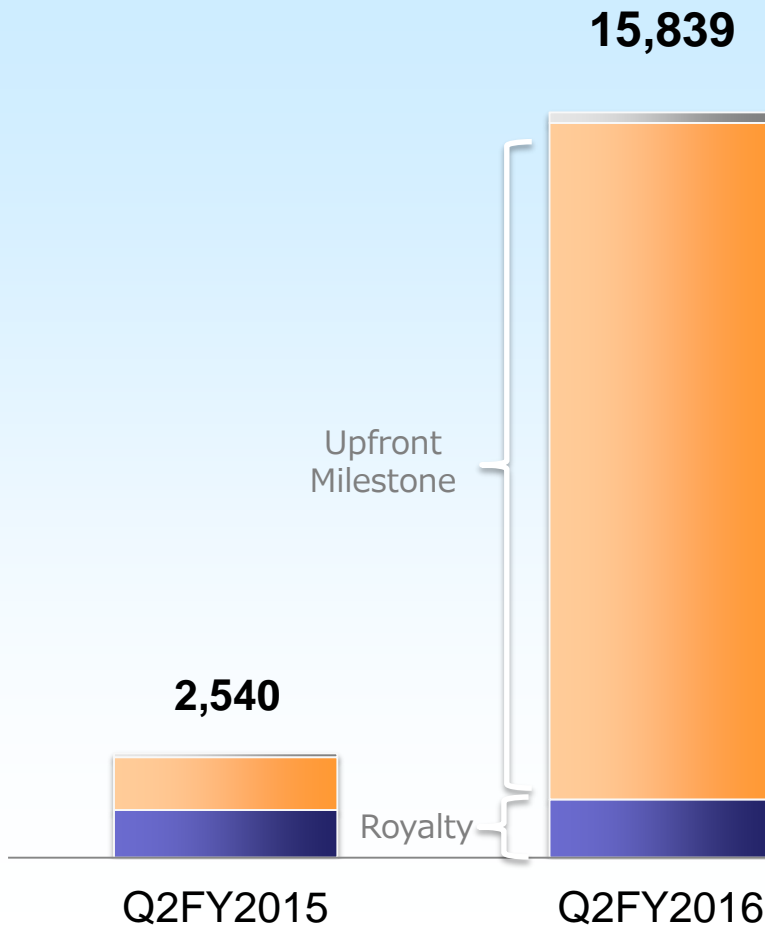
## Q2 Consolidated Results for FY2016 (IFRS)

(million yen)

	Q2 FY15	Q2 FY16	%change	FY16 Forecast	Progression
Revenue	2,540	15,839	523%	27,925	56%
Gross Profit	2,540	15,839	523%	-	
R&D expenses	1,896	1,657	-13%	7,074	23%
SG&A expenses	1,440	2,069	44%	4,027	51%
Operating income (loss)	(753)	12,223	-	17,096	71%
Net income before tax(loss)	(1,418)	13,245	-	14,901	88%
Net income attributable to owners of the parent company	(1,128)	10,716	-	13,064	82%
	March 31 <sup>th</sup> 2016	September 30 <sup>th</sup> 2016	Change		
Cash & cash equivalents	10,068	15,680	+5,612		

# Revenue

(million yen)



## Significant Revenue Growth

- Upfront payment of \$125 million from Allergan for Muscarinic program
- Milestone payment of \$10 million from AstraZeneca for initiation of PI trials for A<sub>2A</sub> receptor antagonist

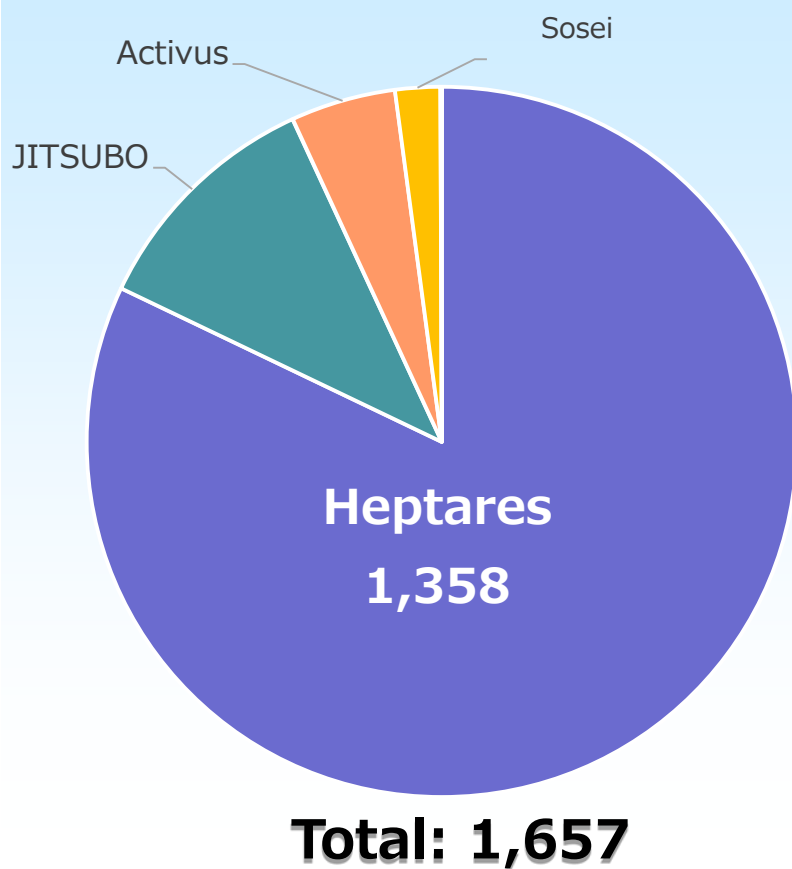
- The growth of Seebri<sup>®</sup> and Ultibro<sup>®</sup> in the first half of the year has generated royalty growth of approximately 28%

\* Seebri<sup>®</sup> Breezhaler<sup>®</sup> and Ultibro<sup>®</sup> Breezhaler<sup>®</sup> are registered trademarks of Novartis AG.

## R&D Expenses and SG&A Expenses

(million yen)

### R&D Q2 2016



(million yen)

R&D	Q2 FY15	Q2 FY16	% change
Heptares	1,678	1,358	87%
JITSUBO	75	182	242%
Activus	108	79	73%
Sosei KK	34	35	102%
<b>Total</b>	<b>1,896</b>	<b>1,657</b>	<b>87.3</b>

(million yen)

SG&A	Q2 FY15	Q2 FY16	% change
Personnel	468	815	174%
Legal, professional	283	561	198%
Other	688	692	101%
<b>Total</b>	<b>1,440</b>	<b>2,069</b>	<b>143%</b>

## **FY2016 Financial Forecast**

**No changes to the full year forecast**

**Business is progressing well, variables that could impact full year forecast include;**

- Continued volatility of the FX rates**
- Timing of milestone payments**
- Progression of licensing activities**

## **2. Business Highlights (Q2 FY2016)**



## Business Highlights

### Excellent progress across all segments

#### Sosei R&D Ltd.

**-Steady growth of royalty revenue stream from COPD products**

	Q3 2016 USD m	Q3 2015 USD m	% change	
			USD	cc*
<i>Ultibro Breezhaler</i>	95	66	44	38
<i>Seebri Breezhaler</i>	37	38	-3	-2

\*Based on Novartis Q3 and 9M 2016 Condensed Interim Financial Report

\*cc (constant currency), an exchange rate that eliminates the effects of exchange rate fluctuations

**Seebri® Breezhaler®**(LAMA; Development code: NVA237)

**Ultibro® Breezhaler®**(LAMA/LABA; Development code: QVA149)

#### Sosei Co. Ltd.

**-Completion of Ph3 clinical trial in Japan for SO-1105 (Oropharyngeal candidiasis)**

\*NDA submission will be expected in the 2<sup>nd</sup> half of this fiscal year



**-Preclinical progress with APP13002 (infectious eye diseases) APP13007 (inflammatory eye diseases)**

## Business Highlights

### Excellent progress across all segments

*Jitsuba*

**-Joint development and commercialization for Animal Ghrelin with Dai Nippon Sumitomo on August 18<sup>th</sup>**

**-Joint development of novel GPCR-targeting peptide candidates with Heptares on November 10<sup>th</sup>**

**-2.5bn yen fundraising has completed successfully through Third-Party Allotment on November 11<sup>th</sup>**

 SOSEI CVC

**-Launched RMF1 on June 23<sup>rd</sup>**

\*First investment will be expected in the 2<sup>nd</sup> half of this fiscal year.



## Business Highlights

### Heptares is Key Driver of Growth Acceleration

#### Allergan/Heptares agreement

**April 2016: Develop & commercialize novel therapeutic drugs for Alzheimer's and other neurological diseases with Allergan**

Allergan has received exclusive rights to develop and commercialize broad clinical and preclinical portfolio of M<sub>1</sub>, M<sub>4</sub> and dual M<sub>1</sub>/M<sub>4</sub> agonists for the treatment of major neurological diseases including Alzheimer's disease

**Heptares has received upfront payment of \$125 million**

#### Astra Zeneca: Initiation of Ph1

**Aug 2015: Agreement with AstraZeneca to develop cancer treatments**

Heptares has granted AstraZeneca exclusive global rights to develop, manufacture and commercialise the adenosine A<sub>2A</sub> receptor antagonist, HTL1071, a small molecule immuno-oncology candidate, and potential additional A<sub>2A</sub> receptor-blocking compounds.

**Initiation of Phase 1 clinical study triggered a \$10 million milestone payment**

## **3. Mid to Long term Strategy**

## 3. Mid to Long term Strategy

**To become a global Biotech Company,  
anchored in Japan**

- I.** Operational Priorities  
(Organic/Inorganic)
- II.** Financial Profile and outlook
- III.** Business Model Evolution

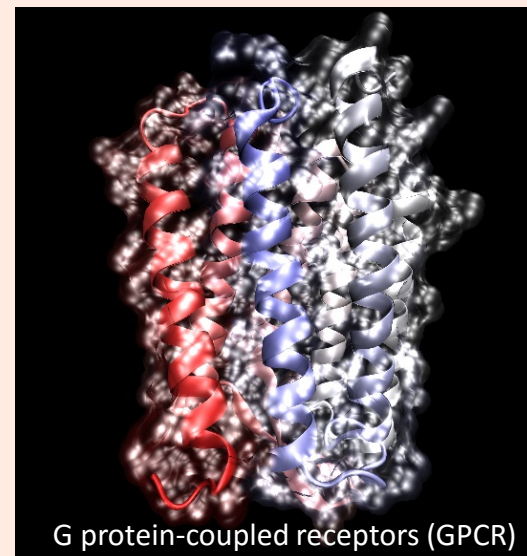


## I .Operational Priority: Organic growth led by Heptares

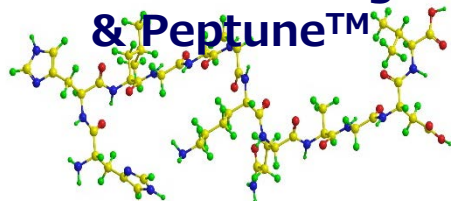


Structure based drug design and development using Heptares StaR<sup>®</sup> technology is at the centre of Sosei's organic growth and development strategy, we will look to;

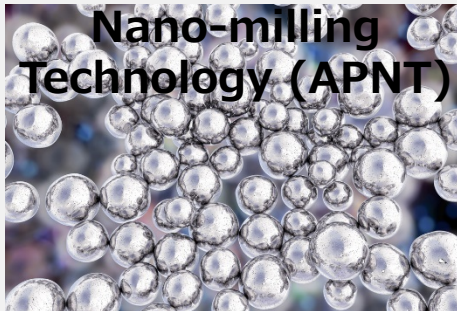
- Strengthen our science and technology leadership
- Expand and advance a broader pipeline of novel
- Extend internal development regulatory and commercial capabilities



Molecular Hiving<sup>™</sup>  
& Peptune<sup>™</sup>











Nano-milling  
Technology (APNT)



Sosei Co. Ltd.

Focus on  
Development in  
Japan such as  
SO-1105

## Heptares Impact: Expand and Advance a Broader Pipeline (Multiple revenue stream opportunities)

	Product/Programme	Indication	Partner	Discov.	Preclin.	Phase 1	Phase 2	Phase 3	Market	
Sosei	<b>Products /Development Pipeline (Sosei)</b>									
	Seebri®/Ultibro®	COPD	 NOVARTIS							
	QVM 149	Asthma	 NOVARTIS							
WAVE 1	<b>Wave 1: Partnered Pipeline (Heptares)</b>									
	M <sub>1</sub> agonist	AD/Sz Cognition	 Allergan							
	M <sub>4</sub> agonist	AD/Sz Psychosis	 Allergan							
	M <sub>1</sub> M <sub>4</sub> dual agonist	Sz/AD Psych / Cog	 Allergan							
	A <sub>2A</sub> antagonist	Cancer I/O	 AstraZeneca							
	CGRP antagonist	Migraine	 TEVA							
WAVE 2	<b>Wave 2: Proprietary Pipeline (Heptares)</b>									
	mGlu <sub>5</sub> NAM	Neurology								
	Orexin OX <sub>1</sub> antagonist	Addiction								
	Orexin OX <sub>2</sub> agonists	Narcolepsy								
	Anti-PAR2 mAb	Atopic Dermatitis								
	GLP-1 antagonist	Hyperinsulinism								
	Multiple targets (mAbs)	Immuno-oncology	 kymab							
	Multiple targets (SMEs)	Multiple indications								

## I .Operational Priority: Inorganic growth through M&A

**Targeted M&A and in-licensing remains important part of inorganic growth strategy**



**STRENGTHEN** discovery, development, and commercialisation technologies and capabilities



**COMPLEMENT** existing technologies and capabilities



**ACCELERATE** delivery; e.g. in-licensing of late stage candidates



**Effective  
Strategy  
Delivery**



## II. Financial Profile and Outlook

### 1. Strong financial profile

- ✓ Milestone and royalty revenues received from licensed COPD products (Novartis)
- ✓ >\$175m generated in equity, upfront and milestone payments from Heptares partners
- ✓ Strong and flexible balance sheet – well-placed to access equity debt or capital markets

### 2. Robust long-term revenue outlook

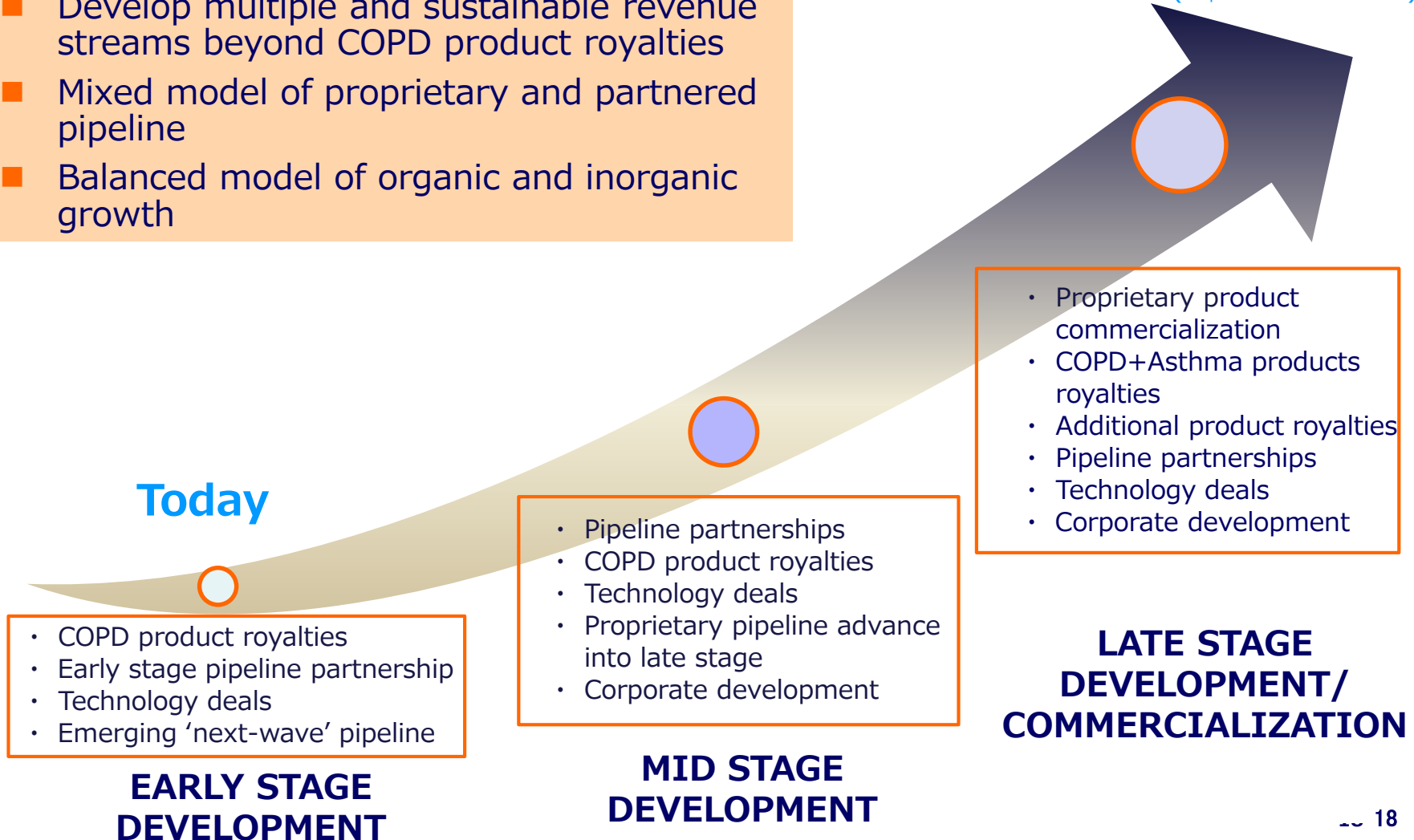
- ✓ Novartis – continued milestones plus royalties from Seebri<sup>®</sup>, Ultibro<sup>®</sup> and potentially QVM149 triple in asthma
- ✓ Current Heptares partnerships - potential to generate up to \$6.1bn in future milestones, plus royalties
- ✓ Future revenues from proprietary and partnered pipeline

### III. Business Model Evolution

Building a leading global Biotech Company

- Develop multiple and sustainable revenue streams beyond COPD product royalties
- Mixed model of proprietary and partnered pipeline
- Balanced model of organic and inorganic growth

**Tomorrow** (>\$10bn Valuation)





**Thank you!**

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## Disclaimer

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# Q&A