



Sosei Group Corporation

FY2015 Results Conference Call

13 May 2016

www.sosei.com

Financial Highlights FY2015

Business Highlights FY2015

Strategy

Consolidated Results for FY2015 (IFRS)

(million yen)

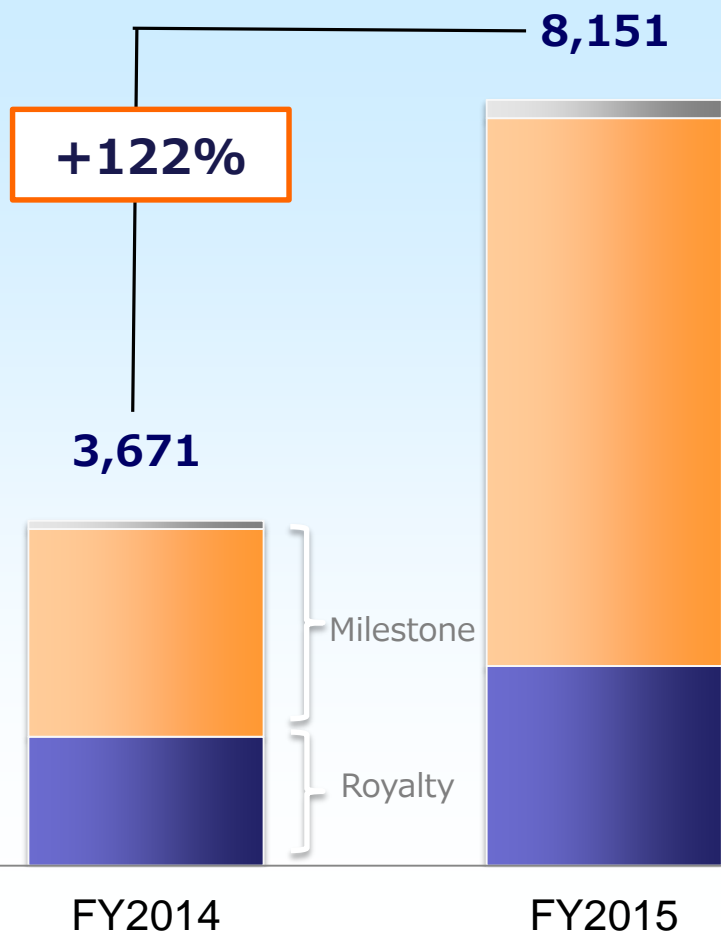
	FY 2014	FY 2015	Change (%)
Revenue	3,671	8,151	122.0%
Gross profit	3,602	8,147	126.1%
R&D expenses	557	3,916	603.0%
SG&A expenses	2,011	3,293	63.7%
Operating income	1,043	1,075	3.0%
Net income (loss)	1,301	(3,297)	—
Net income attributable to owners of the parent company	516	(1,432)	—

(million yen)

	FY 2014	FY 2015	Change
Cash and cash equivalents	5,573	10,068	4,495

Revenue

(million yen)



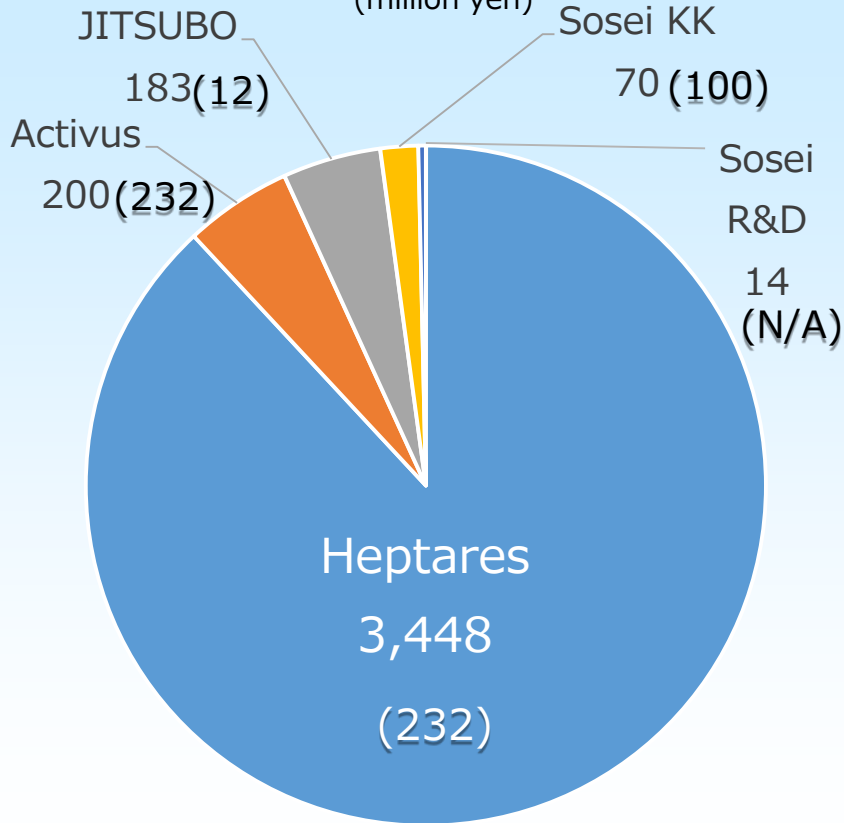
- **122% increase in revenue relative to the comparative period of the last financial year**
 - **The growth of Seebri® and Ultibro® has brought an increase in royalties**
 - **Upfront payments of USD 10 million were received from both AstraZeneca for A_{2A} receptor antagonist and Teva for CGRP, and USD22.5 million was received from NVS upon FDA approval**

* Seebri® Breezhaler® and Ultibro® Breezhaler® are registered trademarks of Novartis AG.

R&D Expenses and SG&A Expenses

R&D 2015

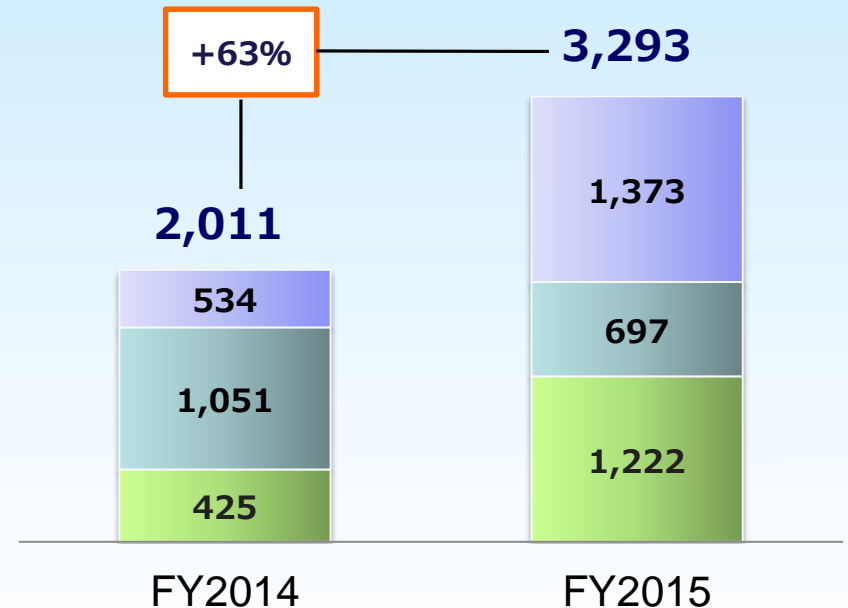
(million yen)



* FY2014 figures shown in parentheses

SG&A expenses

(million yen)



■ Other ■ Outsourcing ■ Personnel

FY2016 Financial Forecast

(million yen)

	FY2015 (actual)	FY2016 (budget)
Revenue	8,151	27,925
Operating income	1,075	17,096
Income before tax	(3,297)	14,901
Net income attributable to owners of the parent company	(1,432)	13,064
R&D expenses	3,916	7,074
SG&A expenses	3,293	4,027

➤ Revenue

- Royalties from Seebri and Ultibro
- Upfront from Allergan
- Initial payments and milestones related to Heptares product candidates

➤ R&D expenses

- Increase investment in development of high-potential products

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FY2015 Achievements



Significant subsequent events

Apr. 2016 **Agreement to develop and commercialize novel therapeutic drugs for Alzheimer's and other neurological diseases with Allergan**



Collaboration with big pharmaceutical companies

Aug. 2015 **Adenosine A2A receptor antagonist with AstraZeneca**

Nov. 2015 **Discover and Develop Novel Small Molecule CGRP Antagonists for Treatment of Migraine with Teva**

Nov. 2015 **Strategic Drug Discovery Collaboration with Pfizer**



Milestone & Royalty from Seebri[®] & Ultibro[®]

Growing Royalties from Seebri[®] and Ultibro[®]

Approved in the US October 2015

Heptares Muscarinic Programmes

➤ **M₁ agonists – Cognitive impairment in AD and SZ**

- HTL9936 – first-in-class oral agent
- Phase 1a completed (84 healthy volunteers)
- Confirmed safety, tolerability, PK
- Increased brain activity w/o AEs linked to M₂/M₃ binding
- Phase 1b underway, further clinical studies planned

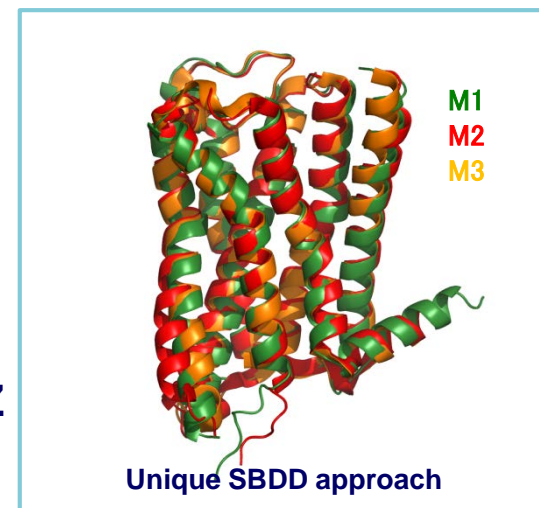
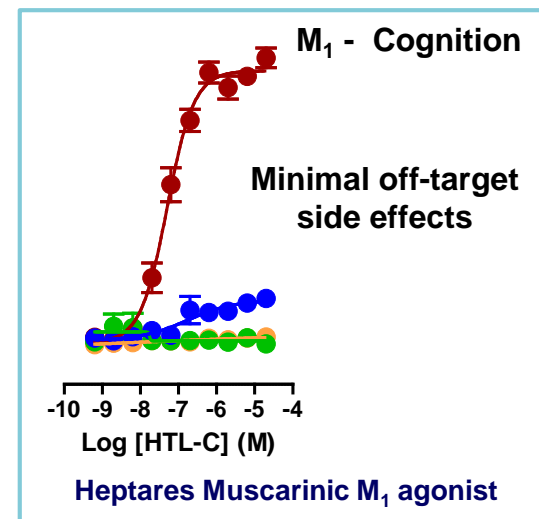
➤ **M₄ agonists – Psychosis and behavioural disturbance**

- Potential in SZ and Alzheimer's disease
- Highly selective for M₄, optimised pharmacology
- In preclinical stage; first clinical studies being planned

➤ **Dual M₁/M₄ agonists – Cognitive impairment & Psychosis**

- In preclinical stage; first clinical studies being planned

➤ **Addresses high unmet medical needs in AD and SZ**



Significant subsequent events

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

- Allergan receives exclusive rights to develop and commercialize broad clinical and preclinical portfolio of M1, M4 and dual M1/M4 agonists for the treatment of major neurological diseases including Alzheimer's disease
- Heptares will receive upfront payment of USD \$125m, milestone payments of up to approximately \$665m associated with the successful Ph1, 2 & 3 clinical development and launch of the first three licensed compounds and approximately \$2.5bn associated with achieving certain annual sales. In addition, Heptares is eligible to receive up to double-digit tiered royalties on net sales of all products resulting from the partnership
- Allergan commits up to \$50m to a R&D program to be conducted jointly by Allergan & Heptares, and will be responsible for the development of licensed compounds upon initiation of Ph2b studies and for subsequent manufacturing and commercialization

Adenosine A_{2A} Antagonist in cancer immunotherapy

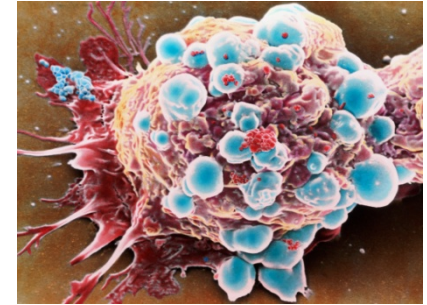
➤ Breakthrough in cancer immunotherapy

- HTL1071 – a novel adenosine A_{2A} antagonist optimised for cancer indications, plus other compounds
- \$500m partnership with AstraZeneca (Aug 2015)
- Best in class qualities and has high chance of being first in class for cancer – IND open

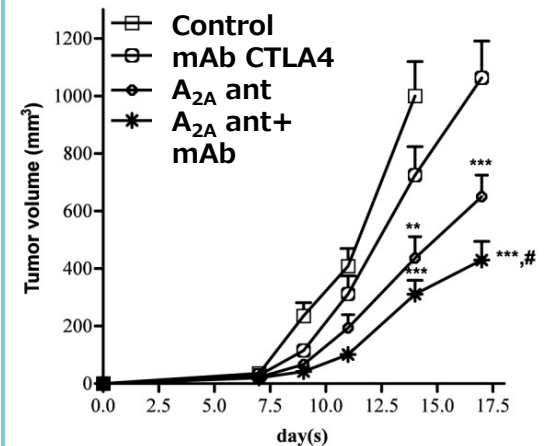
➤ Adenosine production is one of many ways tumour cells evade the immune system

➤ A_{2A} antagonists block action of adenosine on T cells and have potential to increase efficacy of immunotherapies

- Potential to combine with multiple immunotherapy approaches e.g. checkpoint inhibitors, cancer vaccines, CAR-T
- Opportunity in a wide range of tumour types
- Ability to select patients based on biomarkers of elevated adenosine e.g. CD73



T cell killing a cancer cell. Blocking A_{2A} receptors on T cells prevents tumours evading the immune system



A_{2A} antagonists enhance the efficacy of other immunotherapies, e.g. CTLA4 and PD1 mAbs

*Modified from Fig. 1, Ioannone, et al. Am. J. Cancer Res. (2014)

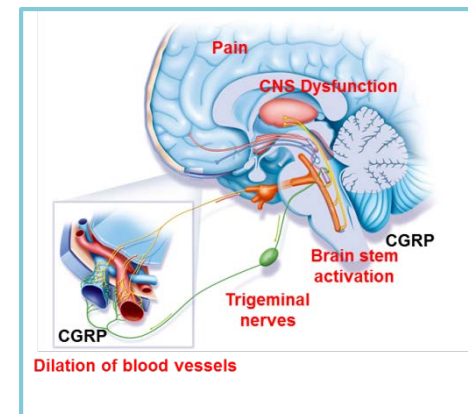
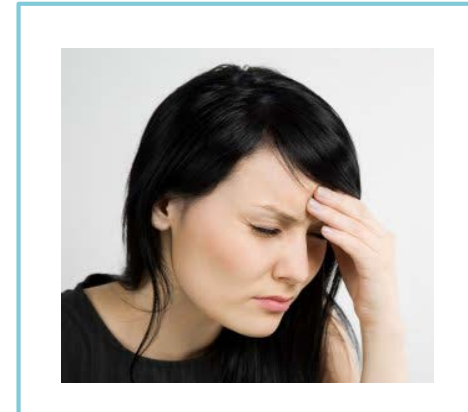
AstraZeneca/Heptares agreement

Aug 2015: Agreement with AstraZeneca to develop cancer treatments

- Sosei will grant AstraZeneca exclusive global rights to develop, manufacture and commercialise the adenosine A_{2A} receptor antagonist, HTL1071, a small molecule immuno-oncology candidate, and potential additional A_{2A} receptor-blocking compounds.
- The companies will also collaborate to discover further A_{2A} receptor-blocking compounds for development in cancer immunotherapy.
- Upfront payment of USD \$10m, potentially more than \$500m in development and sales milestones, and royalties on net sales.

Small Molecule CGRP Antagonists for Migraine

- **Highly potent, small molecule CGRP antagonists**
 - \$410m partnership with Teva (Nov 2015)
 - In preclinical stage; first clinical studies being planned
- **CGRP antagonism is a clinically validated approach in migraine**
 - CGRP antibody programs prevalent in industry
 - Need for well tolerated, higher potency small molecule drug – non-invasive, easily reversible
- **Addressing significant unmet medical needs**
 - Novel modality offers treatment option to larger patient population (incl. triptan-refractory or intolerant, or CV risk)
 - Opportunity to develop agents for prophylaxis, rescue and acute therapy



Teva/Heptares agreement

Nov 2015 : Agreement with Teva to Discover and Develop Novel Small Molecule CGRP Antagonists for Treatment of Migraine

- **Teva will receive exclusive global rights to develop, manufacture and commercialize novel CGRP antagonists.**
- **World-leading clinical and commercial partnership in migraine**
- **Upfront payment of USD \$10m and research funding, potentially up to \$400m in development and commercialization milestones, and royalties on net sales.**

Strategic Drug Discovery Collaboration and Equity Agreement with Pfizer

Nov 2015 : Heptares/Pfizer agreement focused on 10 GPCR targets across multiple therapeutic areas and Sosei/Pfizer KK equity agreement

➤ Strategic Drug Discovery Collaboration

- Heptares will support the discovery of potential novel agents directed to the GPCR targets selected by Pfizer
- Pfizer will be responsible for developing and commercializing any potential therapeutic agents
- Potentially up to \$189m per target in research, development, regulatory and commercializing, and royalties on net sales.

➤ Equity agreement

- Sosei and Pfizer KK have entered into an equity agreement under which Pfizer KK will purchase \$33m of newly issued Sosei common stock at a premium of 25%
- Enhance the relationship with Pfizer and accelerate the delivery of potential new therapies to patients

Growing Royalties from Seebri[®] and Ultibro[®]

➤ Seebri^{®1} (LAMA; Development code: NVA237)

- Licensed to Novartis in 2005
- Approved in over 80 countries including the EU and Japan
- **Approved in the US October 2015 (Seebri[™] Neohaler^{®1} administered twice daily)**

➤ Ultibro^{®1} (LAMA/LABA; Development code: QVA149)

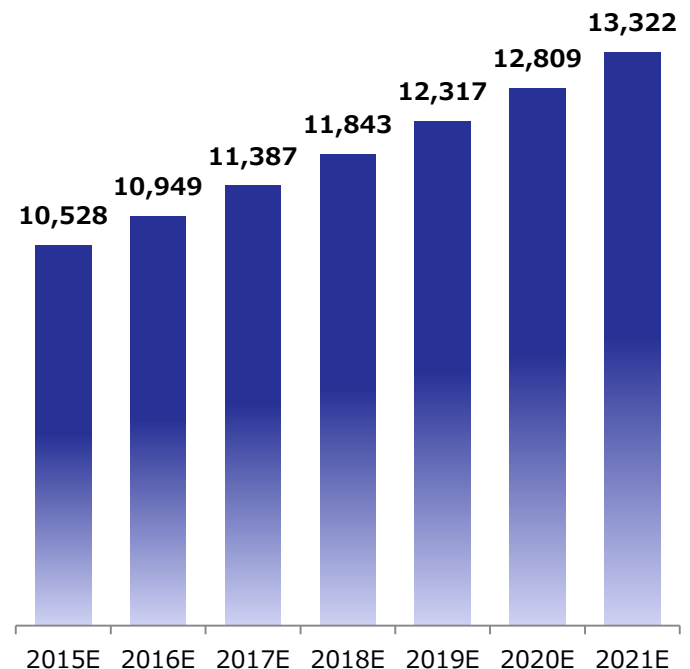
- Approved in over 70 countries including the EU and Japan
- **Approved in the US October 2015 (Utibron[™] Neohaler^{®1} administered twice daily)**
- Also filed for approval in China

➤ Potential development and sales milestones up to USD 187.5mn²

Approximately 50% of milestones received

COPD market forecast

(USD millions)



Source : Pharmacor

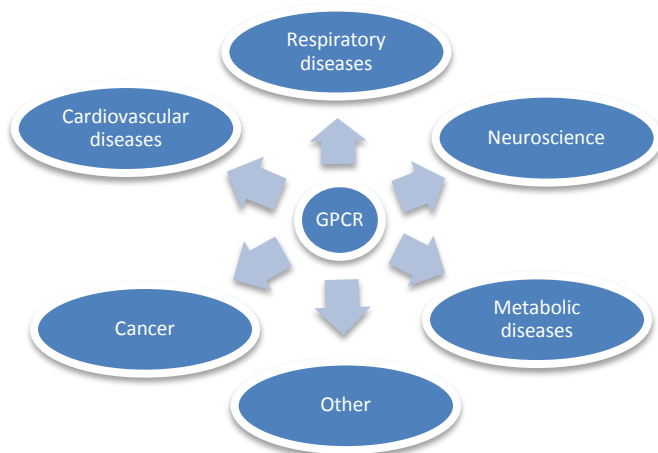
¹ Seebri[®], Ultibro[®], Breezhaler[®] and Neohaler[®] are registered trademarks of Novartis AG. Seebri[™], and Ultibro[™] are trademarks of Novartis AG.

² Maximum potential milestones under the terms of agreement with Novartis¥

Heptares Therapeutics Ltd GPCR-targeted Drug Discovery and Development

G Protein-Coupled Receptor (GPCR) Super Family

- **Most important family of drug targets in industry**
 - Seven transmembrane protein with crucial role in many biological processes
 - 375 GPCRs in 3 major subfamilies (Class A, B, C)
 - 225 with known ligands, 150 orphan targets
- **Clinical validation & compelling biology across a wide range of diseases**
- **Source of approx. 40% of approved drugs***

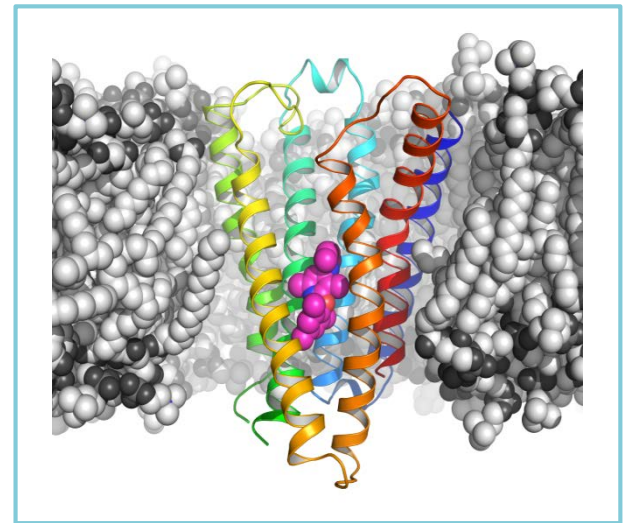


Respiratory diseases	Neuroscience	Cardiovascular diseases
Advair®	Zyprexa®	Opsumit®
Zyrtec®	Abilify®	Diovan®
Breo™ Ellipta™	Seroquel®	Benicar®
Anoro®	Suboxone®	Tracleer®
Seebri®		Zioptan™
Ultibro®	Metabolic diseases	Plavix®
Ventolin® HFA	Belviq®	
Singulair®	Byetta®	
Spiriva®	Myrbetriq®	Cancer
Tudorza® Pressair®	Signifor®	Erivedge®

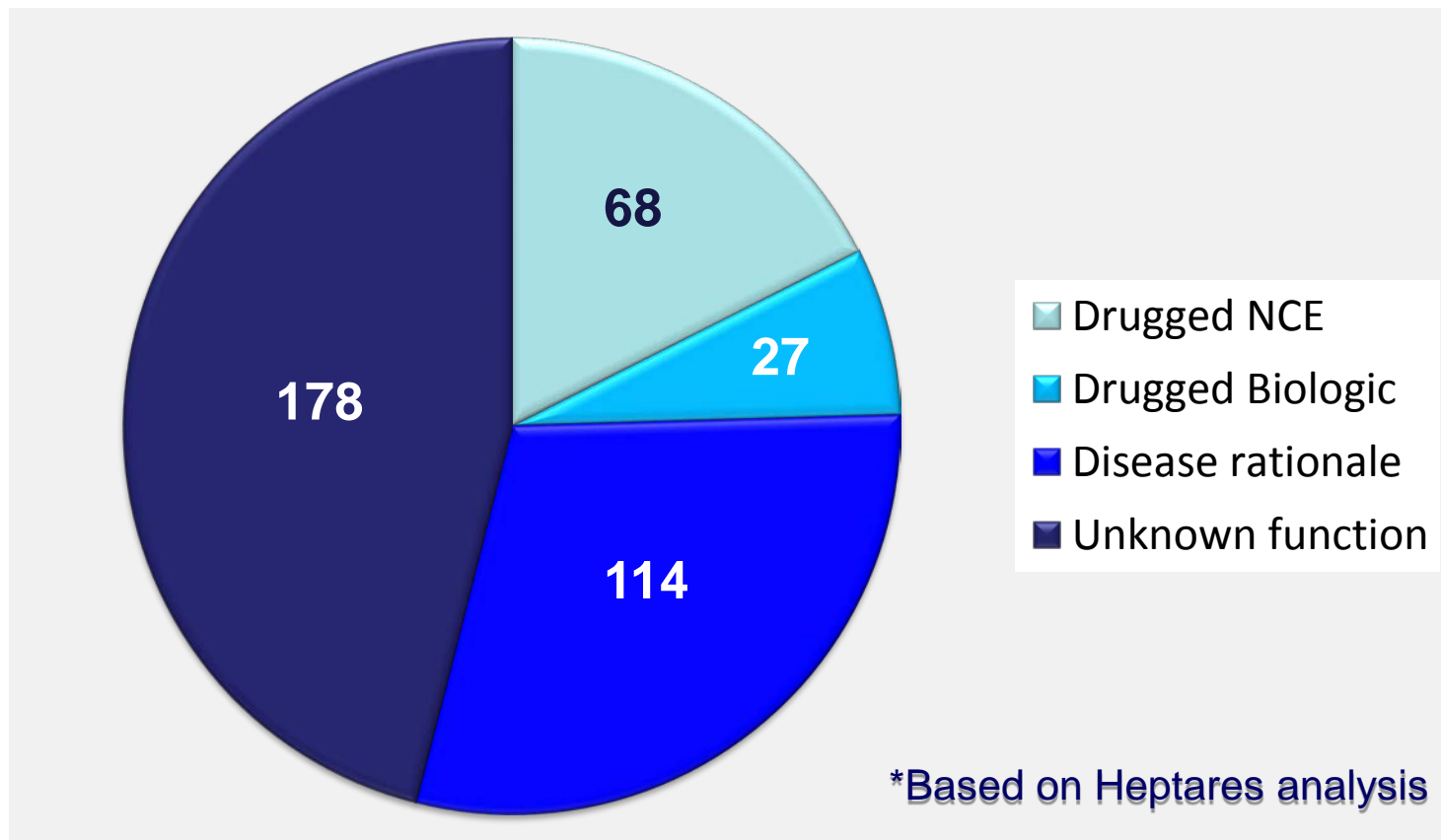
*Product names are trademarks of their respective owners

Major Opportunity Targeting GPCRs








- **GPCRs are not optimally drugged**
 - Limited potency and selectivity
 - Metabolic and safety liabilities
 - Inadequate route of administration
 - **Many high-value targets remain untapped or intractable**
 - First-in-class and superior medicines required
 - Dynamic area with new biology constantly emerging
 - Small molecules and biologics
 - **GPCRs inaccessible to many conventional discovery approaches**
 - Native GPCR spans cell membrane – highly unstable when removed
- ➔ **Stable GPCRs and 3D structures are the key to unlocking GPCR discovery**



GPCRome



Pipeline: Sosei Co.Ltd., Activus, Jitsubo

	Indication	Preclinical	Ph1	Ph2	Ph3	Approval	Launch	
Sosei Co. Ltd.	SO-1105 Oropharyngeal candidiasis						Registered in 24 European countries, the U.S., and Korea	
	JIT2001 Cardiovascular disease						Making use of Jitsubo's Molecular Hiving	
	JIT1007 Orphan disease							
	APP13002 Infectious eye diseases						Making use of Activus Pure Nanoparticle Technology	
	APP13007 Inflammatory eye diseases							

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Business Highlights FY2015

Strategy

Introduction



Peter BAINS

Representative Executive Officer and
Chief Operating Officer (COO)

Profile

1986 -2009: GlaxoSmithKline

March 1996: General Manager of SmithKline Beecham plc. (GlaxoSmithKline)

January 2001: Senior Vice President, GlaxoSmithKline International Commercial Development

2010 -2016: Syngene International Limited.

January 2010: Board Director and CEO

*Led successful IPO on Mumbai Exchanges in 2015

2010 to date: Sosei Group Corporation

June 2010: Non-executive Director 2010 (to March 2016)

February 2015: Board Director at Heptares
April 2016 COO/CEO-elect

Management Team

Board Directors	Shinichi TAMURA	Board Director	Former Representative Director (CEO) of Genentech Ltd., Japan
	Peter BAINS	Board Director	Former GlaxoSmithKline, Senior Vice President International Commercial Development Former Syngene International Limited., CEO
	Takuya FUJII	External Director	Chairman of Promontory Financial Group Global Services Japan, LLC Former Director-General, Bank of Japan
	Declan DOOGAN, M.D.	External Director	CEO of Portage Biotech Inc. Former Pfizer Inc, Head of Worldwide Development
	Tomohiro TOHYAMA	External Director	Co-founding Partner, TMI Associates

Executive officers	Shinichi TAMURA	Representative Executive Officer, CEO	
	Peter BAINS	Representative Executive Officer, COO	
	Malcolm WEIR	Executive Vice President, Chief R&D Officer	Heptares CEO Former Head of Molecular Science Division, Glaxo Wellcome
	Fiona MARSHALL	Executive Vice President, CSO	Heptares CSO Former Head of Molecular Pharmacology Department, Glaxo Wellcome
	Hidetoshi TORAMI	Executive Vice President, CFO	Former Business Controller, Honeywell Specialty Materials Japan Inc

Sosei : Strategic framework

- **Vision and Mission**
- **Operational Priorities**
 - **Organic**
 - **Inorganic**
- **Business Model Evolution**

Sosei Vision and Mission

Vision

- To become a leading global biopharmaceutical company, anchored in Japan.

Mission

- To discover, develop and deliver new and innovative medicine
- To make a significant contribution to improving the health and quality of life of people around the world
- To deliver superior, long-term shareholder value

Organic Priority and Focus; Leveraging Heptares world leadership in GPCR Structure based drug design and development

Structure based drug design using StaR@ technology is at the centre of Sosei's organic growth and development strategy

STRENGTHEN science and technology leadership through internal investment in Heptares (GPCR SBDD)

- ORBIT collaborations
- Cryogenic Electron Microscopy

EXPAND and advance a broader pipeline of novel, FIC and BIC molecules targeting both blockbuster and rare/orphan indications for both proprietary and partnered opportunities.

EXTEND internal development, regulatory and commercial capabilities to capture greater value in select areas where opportunity exists to take projects further through development, and potentially to the market












G protein-coupled receptors (GPCR)



Heptares Laboratory

Heptares Pipeline

	Programme	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
Heptares targets	M ₁ agonist	AD/Sz Cognition	▶				 Allergan  Allergan  Allergan  AstraZeneca 
	M ₄ agonist	AD/Sz Psychosis	▶				
	M ₁ M ₄ dual agonist	Sz/AD Psych / Cog	▶				
	A _{2A} antagonist	Cancer immunotherapy	▶		IND open		
	CGRP antagonist	Migraine	▶				
	mGlue5 NAM	Neurology	▶				
	Orexin OX ₁ antagonist	Addiction	▶				
	Anti-PAR2 mAb	Multiple indications	▶				
	GLP-1 antagonist	Hyperinsulinism	▶				
	Undisclosed	Orphan CNS	▶				
	Multiple targets (SMEs)	Multiple indications	▶				
	Multiple targets (mAbs)	Multiple indications	▶				
					AD: Alzheimer's disease; Sz: schizophrenia		
Technology partnerships	Up to 10 targets (SMEs/mAbs)	Multiple indications					 Pfizer  AstraZeneca  MedImmune, Inc.  morphosys ³
	Multiple targets (SMEs)	Multiple indications					
	Multiple targets (mAbs)	Multiple indications					
	Multiple targets (mAbs)	Multiple indications					



Inorganic Priority and Focus

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

STRENGTHEN drug discovery, development and commercialisation capabilities, and pipeline

COMPLEMENT existing technologies and functions

ACCELERATE delivery of vision (e.g. selective in-licensing of later stage candidates)



**Effective strategy
delivery**

Business Model

Building a leading global biopharmaceutical 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

>USD10bn

~USD4bn

- COPD product royalties
- Pipeline partnership
- Technology deals
- Emerging 'next-wave' pipeline

SHORT-TERM

- Pipeline partnerships
- COPD product royalties
- Technology deals
- Proprietary pipeline advance
- Platform enhancement
- Corporate development

MID-TERM

- Own product commercialization
- New product royalties
- Pipeline partnerships
- Technology deals
- Platform enhancement
- Corporate development

LONG-TERM



Thank you for your time!

Disclaimer

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Q&A